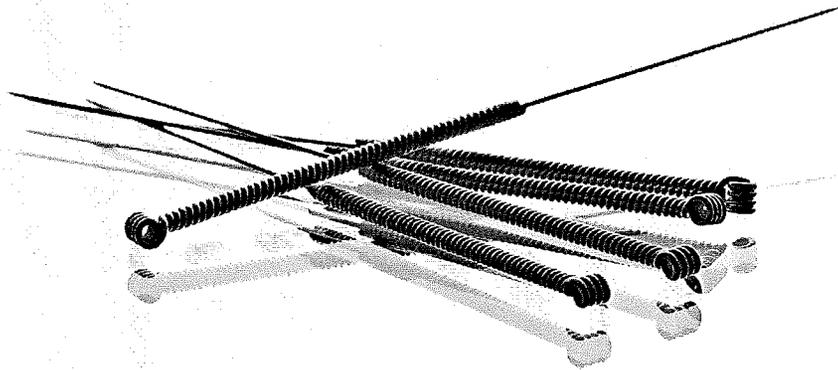




**National
Certification
Commission for
Acupuncture and
Oriental
Medicine**



**NCCAOM®
Study Guide
For Diplomate In
Acupuncture Certification**



2015

2015
NCCAOM® Examination Study Guide for the
Diplomate of Acupuncture Certification



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Introduction

This study guide is designed to help prepare candidates for the NCCAOM certification examinations. Passage of the NCCAOM certification examinations is one of the requirements to become a Diplomate of Acupuncture (NCCAOM). Academic program officials from the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) accredited Oriental medicine programs will also benefit from reviewing the content in this guide. The *NCCAOM[®] Examination Study Guide for Diplomate of Acupuncture* has all the examination preparation materials and information published by the NCCAOM in one document.

Candidates for NCCAOM Certification in Acupuncture are applicants who have met all of the academic and/or training requirements for NCCAOM[®] Certification in Acupuncture. Candidates for NCCAOM certification have qualified by one of the established eligibility routes published in the *NCCAOM[®] Certification Handbook*. The latest edition of this handbook is available on the NCCAOM website at www.nccaom.org.

All candidates for certification have completed a minimum number of hours of academic course work to qualify to take each required examination (see chart below). Completion of these hours of course work qualifies the applicant to sit for the following Acupuncture Certification Examinations as a “pre-graduate.” Additional hours are required for final certification.

Examinations	Completed Hours
Foundations of Oriental Medicine	1,490
Biomedicine	
Acupuncture with Point Location	

In addition to passing the above certification exams all candidates for NCCAOM Certification in Acupuncture must document successful completion of an NCCAOM approved in-person practical clean needle technique (CNT) course. The certificate program in CNT offered by the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) is approved by the NCCAOM. More information is available on their website at www.ccaom.org. The CNT certificate documentation can be submitted any time before or after the candidate has applied to take the NCCAOM certification exams. Please refer to the *NCCAOM[®] Certification Handbook* for more information.

Once all of the above certification examinations are passed there are two more steps to complete the certification process: 1) Notify the CNT vendor to send the CNT certificate to the NCCAOM, and 2) Notify the academic institution to send the final graduation transcripts to the NCCAOM. More information can be found in the *NCCAOM[®] Certification Handbook*.



Examination Development

The NCCAOM examination study guides provide background information on the validation of the NCCAOM certification examinations. The Acupuncture, Chinese Herbology and Oriental Medicine certification programs are currently accredited by the National Commission for Certification Agencies (NCCA). The Acupuncture Certification Program carries the NCCA seal.

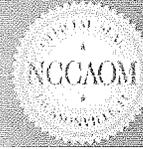


In order for the NCCAOM Certification in Acupuncture Program to remain accredited by NCCA, the NCCAOM must adhere to strict national standards for examination development. All certification exams for the NCCAOM Certification in Acupuncture Program must meet the examination content validity standards set forth by NCCA. The following contains information on validation of the examination content.

The NCCAOM contracts with Schroeder Measurement Technologies, Inc. (SMT) to develop all NCCAOM certification examinations. SMT is a psychometric consulting group that serves to provide all examination development validation studies and scoring for the NCCAOM examinations.

Examination Content Validation

The foundation of a valid, reliable, and legally defensible professional certification program is first the result of a well-constructed job analysis (JA) study. A JA establishes the link between test scores and competencies assessed by the examination and thus the inference that the scores achieved by candidates on the certification examinations are based on valid content. Therefore, all “pass” or “fail” decisions correlate to competency assessment (performance) as measured by the examination. The JA is a process by which tasks performed by NCCAOM certified practitioners and licensed acupuncturists are examined for importance (which considers criticality of the tasks performed and frequency by which the tasks are performed in practice). A minimum of every five years the NCCAOM conducts a JA, in order to update the examination content outlines. Content decisions for the examination content outlines are directly linked to the results of the most recent JA. During the 2013 Job Analysis (JA) study, NCCAOM subject-matter experts (NCCAOM Diplomates who have expertise and experience as an educator or practitioner) provided the list of competency statements for the NCCAOM Acupuncture with Point Location, Biomedicine, Foundations of Oriental Medicine, and Chinese Herbology content outlines. A survey instrument was developed by an NCCAOM appointed JA Taskforce. The survey instrument was provided to currently practicing NCCAOM Diplomates and licensed acupuncturists in order to inquire about the relative “importance” and “frequency” of performing their different job tasks. The survey results were reviewed and interpreted by the JA Taskforce members and the NCCAOM subject-matter experts (SMEs) and, as a result, new content outlines were developed for all NCCAOM certification exams. The 2015 examination content outlines contained in this study guide are based on the 2013 JA. Interpretation of the JA results was based on use of systematic decision criteria. The 2013 JA provides content validity support and linkage to the examination items (i.e., questions on the examinations) for all NCCAOM certification exams for the Acupuncture Certification Program.



This NCCAOM[®] *Examination Study Guide for Diplomate of Acupuncture* provides all the content outlines for each examination required for NCCAOM Certification in Acupuncture. Each content outline lists the percent weightings for each section (i.e., domains) within the outline and gives a detailed list of competency statements for each domain and sub-domain. The listing of the competency statements is included to give the candidate more information about the competency expected for each domain.

Item Writing

The second step in developing a defensible examination program occurs after the content outlines (i.e., test blueprints) are constructed. After a test content outline is developed, examination items are written to match the content outline. Each item must be “linked” to a content area listed on a content outline and written based on the supporting competency statements.

Item writing events held across the country are conducted to assist the NCCAOM[®] Examination Development Committees (EDCs) in developing new items for the certification examinations. The EDCs, composed of a panel of SMEs, representing practitioners and educators from different regions of the United States and from various practice settings, convene for the purpose of writing, reviewing, and revising examination items to meet strict content guidelines and test construction standards. NCCAOM test development staff members and experienced SMEs train the item writers on how to write NCCAOM acceptable multiple-choice items. The goal of the training is to define appropriate item formats, train the SMEs on what is not an appropriate item (e.g., using “none or all of the above” as a distractor, making the key longer or shorter than the distractors, using negatively worded items), and how to review various item types, including the cognitive complexities associated with items.

Item Review

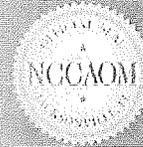
Once new items are written and edited for format, a panel of SMEs meets with a testing staff liaison to review and edit the new items. Once the items are approved by the SMEs, the testing staff enters the item(s) into the appropriate item bank and codes the items as determined by the SMEs according to the content outline specifications. The NCCAOM EDCs meets annually to review the current and new items. Additionally, each question is reviewed for performance statistics (i.e., a psychometric evaluation). When a candidate takes an examination, a small percentage of items are pretested to determine statistics for item difficulty. The statistical evaluation allows the SMEs to see when the correct answer is found by guessing (there are some very specific flags that help us) or if the answer has more than one (or no) correct answers. This is not to say that all exams are perfect, but the NCCAOM applies very strict standards so that every effort is made to avoid errors in the test item.



Examination Administration

All NCCAOM examinations for the Acupuncture Certification Program are given as a computer based administration. The table below provides the examination administration features for the 2015 Acupuncture Certification Program Examinations administered at Pearson VUE Professional Test Centers.

Acupuncture Examinations Administration Features for 2015		
Examinations	Number of Multiple-Choice Items	Allotted Time
Adaptive Exams		
Foundations of Oriental Medicine	100	2.5 Hours
Biomedicine	100	2.5 Hours
Acupuncture with Point Location <i>(concludes September 30, 2015)</i>	100	2.5 Hours
Linear Exam (November 9-21, 2015)		
Acupuncture with Point Location	130	3.25 Hours



2015 Expanded Content Outlines

Based on the JA conducted in February 2013, the content outlines for the Certification in Acupuncture are included below. The competency statements are designed to help guide the candidates in studying for each examination. All of the examinations administered in 2015 will be based on these content outlines. Each competency statement gives the candidate the level of competency expected for the particular content area listed on the outline. Please note that the Acupuncture Certification includes the content outlines for the following examinations: Foundations of Oriental Medicine, Biomedicine, and Acupuncture with Point Location.

The Foundations of Oriental Medicine Expanded Content Outline

(Effective as of February 1, 2014)

Note to Candidate: This document serves as a guide to assist in examination preparation for candidates who have met NCCAOM® eligibility requirements. Below is the content outline for the Foundations of Oriental Medicine examination, along with the competency statements.

DOMAIN I: Clinical Examination Methods (10% of Total Exam)

Collect and recognize clinically significant signs and symptoms.

A. Looking (Wang)

1. Spirit (Shen) appearance (including color)

- Observe outward manifestation of Shen (Spirit) (e.g., complexion, expression, demeanor, and general behavior)
- Identify and relate Shen (Spirit) to pattern/syndrome differentiation*

2. Face, eyes, nose, ears, mouth, lips, teeth, and throat

- Observe normal and abnormal conditions and changes of the face and complexion (including color, moisture, texture, and organ-indicative locations), eyes, nose, ear, mouth, lips, teeth and throat
- Identify and relate facial features to pattern/syndrome differentiation*
- Recognize pathological manifestations of the face, including color, moisture, texture, and organ-indicative locations



3. Tongue (body and coating)

- Observe normal and abnormal manifestations, patterns, conditions, and changes of the tongue and sub-lingual area
- Identify and relate features of the tongue to pattern/syndrome differentiation*
- Recognize pathological manifestations of the tongue and tongue coating, including color, size, moisture, texture, shape, position, movement, organ-indicative locations

4. Physical characteristics of the body

- Observe form, movement, and physical characteristics (e.g., head, hair, neck, back, chest, abdomen, extremities, nails)
- Identify and relate form, movement, and physical characteristics to pattern/syndrome differentiation*
- Recognize pathological significance of form, movement, and physical characteristics
- Observe conditions and changes of the skin
- Identify and relate conditions and changes of the skin to pattern/syndrome differentiation*
- Recognize pathological significance of conditions and changes of the skin
- Observe normal and abnormal excretions (e.g., phlegm, sputum, saliva, sweat, discharge, stool, urine)
- Identify and relate conditions and changes of excretions to pattern/syndrome differentiation*
- Recognize pathological significance of excretions

B. Listening and Smelling (Wen)

1. Sounds

- Listen to respiratory sounds
- Identify and relate respiratory sounds to pattern/syndrome differentiation*
- Recognize pathological significance of respiratory sounds
- Listen to tonal qualities, voice, and speech
- Identify and relate tonal qualities, voice, and speech to pattern/syndrome differentiation*
- Recognize pathological significance of tonal qualities, voice, and speech



- Listen to abdominal sounds
- Identify and relate abdominal sounds to pattern/syndrome differentiation*
- Recognize pathological significance of abdominal sounds

2. Odors

- Smell body odors
- Identify and relate body odors to pattern/syndrome differentiation*
- Recognize pathological significance of body odors
- Smell breath and mouth odors
- Identify and relate breath and mouth odors to pattern/syndrome differentiation*
- Recognize pathological significance of breath and mouth odors
- Smell excretions (e.g., sweat, urine, feces, leukorrhea, flatulence, wound exudates)
- Identify and relate excretions to pattern/syndrome differentiation*
- Recognize pathological significance of excretions

C. Asking (Wen)

1. Chief complaint

- Inquire about presenting complaint (onset, duration, location, nature, alleviation, aggravation)
- Inquire about the history and development of chief complaint
- Identify and relate chief complaint to pattern/syndrome differentiation*
- Identify appropriate additional questions based on examination findings and patients' response to inquiries

2. Current health conditions

- Conduct a review of systems, including the "Ten Questions" (Shi Wen)
- Identify and relate current health conditions to pattern/syndrome differentiation*
- Identify appropriate additional questions based on examination findings and patients' response to inquiries



3. Health history

- Inquire about personal health history, including previous symptoms, diagnoses, and treatments
- Inquire about familial history
- Identify and relate health history to pattern/syndrome differentiation*
- Identify appropriate additional questions based on examination findings and patients' response to inquiries

D. Touching (Palpation) (Qie)

1. Radial pulses (including the 28 Qualities)

- Identify the location of radial pulses
- Identify qualities of radial pulses (including rate, depth, strength, and shape) as indicators of patterns of disharmony and of normal and abnormal states of organ and meridian function
- Identify and relate radial pulses to pattern/syndrome differentiation*

2. Abdomen

- Identify, through palpation, normal and abnormal conditions of the abdomen (e.g., temperature, texture, shape, and pain)
- Identify abdominal regions representing organs and meridians
- Identify and relate abdominal palpation findings to pattern/syndrome differentiation*

3. Meridians

- Identify, through palpation, findings along the meridians (e.g., nodules, tenderness, numbness, temperature, sensitivity)
- Identify and relate meridian palpation findings to pattern/syndrome differentiation*

4. Other body areas

- Identify, through palpation, pain, body sensations (e.g., numbness, tingling, sensitivity), temperature changes, and quality of tissue (e.g., edema, hardness/softness, tension/flaccidity)
- Identify and relate palpation findings to pattern/syndrome differentiation*



*Pattern/Syndrome Differentiation:

- Eight Principles (Ba Geng)
- Organs (Zang Fu)
- Meridian/Channel (Jing Luo)
- Six Stages (Liu Jing)
- Four Levels (Wei, Qi, Ying, Xue)
- Five Elements (Wu Xing)
- Qi, Blood, Body Fluids (Qi, Xue, Jin Ye)
- Triple Burner (San Jiao)

DOMAIN II: Assessment, Analysis, and Differential Diagnosis Based Upon Traditional Chinese Medicine (TCM) Theory (45% of Total Exam)

Formulate a differential diagnosis (Bian Zheng).

A. Knowledge and Application of Fundamental Theory of TCM Physiology (Sheng Li), Etiology (Bing Yin), and Pathogenesis (Bing Ji)

1. Yin/Yang theory (e.g., Interior/Exterior, Cold/Heat, Deficient/ Excess)

- Describe Yin/Yang theory
- Evaluate symptoms according to Yin/Yang theory
- Identify pathologies according to Yin/Yang theory
- Apply Yin/Yang theory to clinical assessment

2. Five Elements theory (Five Phases/Wu Xing)

- Describe Five Elements theory
- Evaluate symptoms according to Five Elements theory
- Identify pathologies according to Five Elements theory
- Apply Five Elements theory to clinical assessment



3. Organ theory (Zang Fu)

- Describe Organ theory
- Evaluate symptoms according to Organ theory
- Identify pathologies according to Organ theory
- Apply Organ theory to clinical assessment

4. Channel theory (Jing Luo) (including regular channels, Extraordinary channels, Luo-connecting channels, divergent channels, muscle channels, and skin regions)

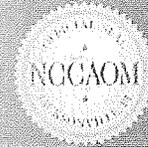
- Describe Channel theory
- Evaluate symptoms according to Channel theory
- Identify pathologies according to Channel theory
- Apply Channel theory to clinical assessment

5. Essential Substances theory [Qi, Blood (Xue), Fluids (Jin Ye), Essence (Jing), Spirit (Shen)]

- Describe Qi, Blood (Xue), Body Fluids (Jin Ye), Essence (Jing), Spirit (Shen)
- Evaluate symptoms according to Qi, Blood (Xue), Body Fluids (Jin Ye), Essence (Jing), Spirit (Shen)
- Identify pathologies according to Qi, Blood (Xue), Body Fluids (Jin Ye), Essence (Jing), Spirit (Shen)
- Apply Qi, Blood (Xue), Body Fluids (Jin Ye), Essence (Jing), Spirit (Shen) to clinical assessment

6. Causes of Disease: External (Six Excesses [Liu Yin]), Internal (Seven Emotions), and Miscellaneous (diet, excessive sexual activity, excessive physical work or lack of exercise, trauma, bites, parasites, Phlegm, Blood stasis)

- Describe Causes of Disease
- Evaluate symptoms according to Causes of Disease
- Identify pathologies according to Causes of Disease
- Apply Causes of Disease to clinical assessment



B. Formulation of a Differential Diagnosis Based upon Chief Complaint (Zhu Su), Prioritization of Major Symptoms (Zhu Zheng), Knowledge of TCM Diseases (Bian Bing), and Pattern Identification (Bian Zheng)

1. Eight Principles (Ba Gang) (i.e., Yin/Yang, Interior/Exterior, Cold/Heat, Deficient/ Excess)

- Describe Eight Principles differentiation
- Assess and analyze signs and symptoms according to Eight Principles differentiation
- Formulate a diagnosis based on the analysis of Eight Principles differentiation

2. Organ theory (Zang Fu)

- Describe Organ pattern differentiation
- Assess and analyze signs and symptoms according to Organ differentiation
- Formulate a diagnosis based on the analysis of Organ differentiation

3. Channel theory (Jing Luo) (including regular channels, Extraordinary channels, Luo-connecting channels, divergent channels, muscle channels, and skin regions)

- Describe Channel theory
- Assess and analyze signs and symptoms according to Channel theory
- Formulate a diagnosis based on the analysis of Channel theory

4. Six Stages (Tai Yang, Yang Ming, Shao Yang, Tai Yin, Shao Yin, Jue Yin)

- Describe the Six Stages differentiation
- Assess and analyze signs and symptoms according to Six Stages differentiation
- Formulate a diagnosis based on the analysis of Six Stages differentiation

5. Four Levels (Wei, Qi, Ying, Xue)

- Describe the Four Levels differentiation
- Assess and analyze signs and symptoms according to Four Levels differentiation
- Formulate a diagnosis based on the analysis of Four Levels differentiation



6. Five Elements (Five Phases/Wu Xing)

- Describe Five Elements differentiation
- Assess and analyze signs and symptoms according to Five Elements differentiation
- Formulate a diagnosis based on the analysis of Five Elements differentiation

7. Qi, Blood, Body Fluids (Qi, Xue, Jin Ye)

- Describe Qi, Blood, Body Fluids differentiation
- Assess and analyze signs and symptoms according to Qi, Blood, Body Fluids differentiation
- Formulate a diagnosis based on the analysis of Qi, Blood, Body Fluids differentiation

8. Triple Burner (San Jiao)

- Describe Triple Burner differentiation
- Assess and analyze signs and symptoms according to Triple Burner differentiation
- Formulate a diagnosis based on the analysis of Triple Burner differentiation

9. Six Excesses (Liu Yin)

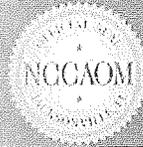
- Describe Six Excesses
- Assess and analyze signs and symptoms according to Six Excesses
- Formulate a diagnosis based on the analysis of Six Excesses

DOMAIN III: Treatment Principle (Zhi Ze) and Strategy (Zhi Fa) (45% of Total Exam)

Formulate treatment principle and strategy based upon differential diagnosis (Bian Zheng).

A. Treatment Principle Based upon Differential Diagnosis

1. Eight Principles (Ba Gang)
2. Organs (Zang Fu)
3. Meridian/Channel (Jing Luo)
4. Six Stages (Liu Jing)
5. Four Levels (Wei, Qi, Ying, Xue)
6. Five Elements (Wu Xing)
7. Qi, Blood, Body Fluids (Qi, Xue, Jin Ye)



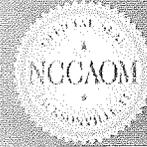
8. Triple Burner (San Jiao)

9. Causes of Disease: External (Six Excesses [Liu Yin]), Internal (Seven Emotions), and Miscellaneous (diet, excessive sexual activity, excessive physical work or lack of exercise, trauma, bites, parasites, Phlegm, Blood stasis)

- Select appropriate treatment principle based on pattern/syndrome differential diagnosis

B. Treatment Strategy to Accomplish Treatment Principle

- Select appropriate treatment strategy (e.g., disperse, tonify, cool, warm) to accomplish treatment principle
- Prioritize treatment focus [e.g., Root and Branch (Biao Ben), acute/chronic, external/internal, Pathogenic Factors, constitutional, seasonal]
- Adjust treatment principle and/or strategy based on patient's response, disease progression, and lifestyle (e.g., substance use, smoking, exercise, diet)



The Biomedicine Expanded Content Outline

(Effective as of February 1, 2014)

Note to Candidate: This document serves as a guide to assist in examination preparation for candidates who have met NCCAOM eligibility requirements. Below is the content outline for the Biomedicine module, along with the competency statements.

Please note: In regards to Clean Needle Technique (CNT), the Biomedicine module focuses on universal precautions and emergency situations in comparison to the Acupuncture with Point Location module which focuses on actual needling and its emergencies (e.g., needle angle and depth).

DOMAIN I: Biomedical Model (90% of Total Exam)

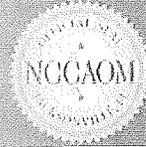
A. Clinical Application of Biomedical Sciences (including anatomy, physiology, pathology, pathophysiology, etc.), Pharmacology, and Nutrients and Supplements **(30%)**

1. Biomedical sciences

- Differentiate normal and abnormal structures and functions of the body systems from the conventional biomedical perspective
- Recognize signs, symptoms, and morbidities associated with common medical conditions
- Demonstrate knowledge of medical terminology

2. Pharmacology

- Recognize functional classifications, mechanisms, side and adverse effects related to commonly used pharmaceuticals **(Refer to Appendix A: Pharmaceuticals)**
- Recognize routes of administration (e.g., intravenous, oral, subcutaneous)
- Demonstrate knowledge of the effects of the use of tobacco, alcohol, and drugs of abuse
- Recognize common, known pharmaceutical-supplement interactions



3. Nutrients and supplements

- Recognize major classifications, known actions, and potential adverse effects related to commonly used nutrients and supplements (**Refer to Appendix B: Nutrients and Supplements**)
- Recognize signs and symptoms associated with abnormal levels of commonly used nutrients and supplements

B. Patient History and Physical Examination (25%)

Understand clinically relevant information gathered through history taking and physical examination.

Candidates are expected to understand all aspects of the physical examination process. They are not expected to be able to perform all aspects of the physical examination themselves.

1. Patient history*

- Conduct a medical interview to obtain patient history
- Organize information obtained during interview into appropriate sections of the patient history
- Distinguish the relevant findings obtained during history taking

*Patient History includes: chief complaint, history of present illness, allergies, past medical history, past surgical history, personal and social history, family history, current medications (prescription and non-prescription), herbs and supplements, review of systems

2. Physical examination

- Identify the components of the physical examination
- Recognize how each portion of the physical examination is performed
- Distinguish the relevant findings obtained from the physical examination



- a. General systems examination (e.g., vital signs, pulmonary, cardiovascular, gastrointestinal, integumentary, etc.)
 - Understand relevant examination techniques such as observation, auscultation, and palpation as applied to each system
 - Recognize how each portion of the general systems examination is performed
 - Distinguish the relevant findings obtained from the general systems examination
 - b. Musculoskeletal examination
 - Understand relevant examination techniques including, but not limited to, range of motion, muscle strength testing, deep tendon reflexes, dermatomal testing, and special tests including orthopedic tests
 - Recognize how each portion of the musculoskeletal examination is performed
 - Distinguish the relevant findings obtained from the musculoskeletal examination
 - c. Neurological examination
 - Understand relevant examination techniques including, but not limited to, assessment of cognitive function, evaluation of cranial nerves, sensory and motor function, and reflexes
 - Recognize how each portion of the neurological examination is performed
 - Distinguish the relevant findings obtained from the neurological examination
3. Imaging, laboratory tests, and other medical studies
- a. Imaging
 - Understand commonly used medical imaging studies (e.g., x-ray, MRI, CT, PET, colonoscopy, cystoscopy, bronchoscopy, etc.)
 - Recognize the significance of information gathered from imaging studies
 - b. Laboratory tests
 - Understand commonly used medical laboratory tests** (e.g., complete blood count, basic metabolic panel, urinalysis, liver panel, cardiac panel, thyroid panel, pregnancy test, and reproductive hormones, etc.)
***normal ranges will not be tested*
 - Recognize the significance of information gathered from laboratory tests



c. Other medical studies

- Understand other commonly used medical studies (e.g., EMG, EKG, etc.)
- Recognize the significance of information gathered from these studies

C. Clinical Assessment Process (30%)

Interpret clinically significant information gathered during history taking and physical examination to recognize pathological conditions. **(Refer to Appendix C: Medical Conditions)**

- Recognize abnormalities in the function of the body systems including, but not limited to, respiratory, cardiovascular, urogenital, reproductive, nervous, integumentary, musculoskeletal, and gastrointestinal systems
- Distinguish between relevant and non-relevant findings
- Recognize typical presentations of commonly encountered medical conditions
- Recognize commonly encountered ominous signs including, but not limited to, medical red flags, mental health red flags, and signs of abuse and trauma

D. Clinical Decision-Making and Standard of Care (5%)

Analyze information to determine appropriate patient management.

- Recognize medical conditions that may be treated without referral
- Recognize medical conditions that require co-management
- Recognize medical conditions that require a referral
- Differentiate the most appropriate type of referral*** (emergent, urgent, or routine), i.e., the timeframe within which the patient should be seen
- Recognize the conventional biomedical prognoses, management, and/or standard of care for common medical conditions **(Refer to Appendix C: Medical Conditions)**

***emergent (immediate) referral; urgent (24 - 48 hours) referral; routine (48 hours - 7 days) referral



DOMAIN II: Office Safety and Professional Responsibilities (10% of Total Exam)

Recognize and implement appropriate office safety standards and demonstrate knowledge of professional responsibilities.

A. Risk Management and Office Safety

- Recognize situations that require special care or emergency management (e.g., burns, seizures, falls, anaphylaxis)
- Implement emergency office protocols including contacting emergency services as appropriate

B. Infection Control

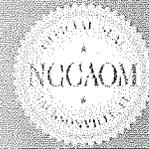
- Identify commonly encountered communicable diseases (e.g., hepatitis, HIV, tuberculosis)
- Identify modes of transmission (e.g., airborne, fecal-oral, vector) and appropriate preventive measurements for common communicable diseases
- Recognize the appropriate office management of commonly encountered communicable diseases and hazardous situations
- Recognize and apply universal precautions

C. Federal Regulations

- Demonstrate knowledge of applicable Occupational Safety and Health Administration (OSHA) and other federal health agencies' requirements
- Demonstrate knowledge of applicable Health Insurance Portability and Accountability Act (HIPAA) requirements

D. Reporting and Record-Keeping

- Demonstrate knowledge of the required contents and maintenance of medical records
- Demonstrate knowledge of mandated reportable conditions (e.g., elder and child abuse, infectious diseases, bioterrorism)
- Demonstrate knowledge of the definition and purpose of ICD, CPT, E&M codes
- Demonstrate knowledge of insurance types and requirements (e.g., general liability, malpractice insurance)



E. Ethics and Professionalism

- Demonstrate knowledge of *NCCAOM*[®] *Code of Ethics* and other ethical principles (e.g., informed consent, conflict of interest, negligence, boundary violations)
- Communicate effectively and professionally with patients, the public, and other healthcare providers



Appendix A: Pharmaceuticals

Appendix A is a list of commonly used pharmaceutical categories. The exam will focus on but may not be exclusively limited to the list below.

- allergy/sinus medications
- angina medications
- antiasthmatic medications
- antibacterial medications
- anticancer medications
- anticoagulant medications
- antidepressants
- antidiabetic medications
- antidiarrheal medications
- antifungal medications
- antihyperlipidemic medications
- antihypertension medications
- anti-nausea medications
- anti-Parkinson medications
- antiprotozoal medications
- antipsychotics
- antiseizure medications
- antiviral medications
- appetite control/weight management medications
- cardiac medications
- central nervous system (CNS) stimulants/attention deficit medications
- cough medications
- drugs of abuse
- gastrointestinal medications
- hormonal replacement therapy
- immune modulators
- mood stabilizer medications
- non-steroidal anti-inflammatory drugs (NSAIDs)
- opioids
- osteoporosis medications
- sedatives, anxiolytic and sleep medications
- sexual dysfunction medications
- smoking cessation medications
- steroids
- stool softeners/laxatives
- thyroid medications
- topical skin medications



Appendix B: Nutrients and Supplements

Appendix B is a list of commonly used nutrients and supplements. The exam will focus on but may not be exclusively limited to the list below.

- amino acids (e.g., L-glutamine, lysine, choline)
- antioxidants (e.g., coenzyme Q10, selenium)
- bone health (e.g., glucosamine sulfate, chondroitin sulfate)
- digestive support (e.g., enzymes, fiber, probiotics)
- hormones (e.g., melatonin, wild yams, DHEA)
- minerals (e.g., calcium, magnesium, potassium)
- mood support (e.g., St. John's Wort, Sam E, 5 HTP)
- vitamins (e.g., A, B1-B12, C, D, E, K)
- Western herbs (e.g., saw palmetto, milk thistle)



Appendix C: Medical Conditions

The conditions (not system headings) listed below are categorized based on how frequently AOM practitioners reported seeing them in the clinical setting per the 2013 Job Analysis. This list is meant to serve as a study guide for the NCCAOM Biomedicine Examination Module to help prioritize focus of study. The exam will focus on but may not be exclusively limited to the conditions below.

The conditions marked with an asterisk (*) signify diseases commonly associated with red flag signs and/or symptoms. Candidates are strongly advised to familiarize themselves with these conditions and the red flag signs and symptoms associated with them.

CATEGORY 1 Frequently Seen Conditions

Cardiovascular

- *Arrhythmias (e.g., atrial fibrillation, premature ventricular contraction, tachycardia, bradycardia)
- *Blood pressure disorders (hypertension and hypotension)
- Atherosclerosis (e.g., coronary artery disease, peripheral vascular disease)

Endocrine and Metabolic conditions

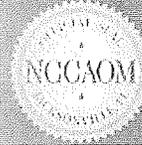
- Thyroid disorders (e.g., Hashimoto's thyroiditis, Graves' disease)
- Pancreatic disorders (e.g., diabetes)
- Obesity
- Hyperlipidemia

Gastrointestinal conditions

- Gastroesophageal reflux disease
- Gastritis
- Inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis)
- Food sensitivity/allergies (e.g., celiac disease, lactose intolerance)
- Irritable bowel syndrome

Mental and Behavioral conditions

- *Mood disorders (e.g., depression, bipolar)
- Anxiety



Musculoskeletal conditions

- Affecting upper extremities (e.g., frozen shoulder, bicipital tendinitis, carpal tunnel syndrome, epicondylitis)
- Affecting lower extremities (e.g., meniscal injuries, compartment syndrome, bursitis)
- Affecting the axial structures (e.g., whiplash, disc herniation, spinal stenosis, spondylolisthesis, TMJ)
- Osteoarthritis
- Osteoporosis

Neurological conditions

- *Stroke
- *Radiculopathies (e.g., nerve root, sciatica)
- Peripheral neuropathy
- Headache (e.g., cluster, tension, migraine, sinus, trauma)
- Sleep disorders (narcolepsy, sleep apnea, insomnia)

Pulmonary conditions

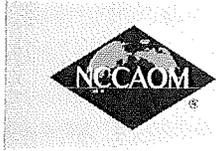
- Asthma
- Respiratory tract infections (e.g., sinusitis, viral infections, strep throat, bronchitis, pneumonia)
- Allergies
- *Pneumothorax

Reproductive conditions

- Menstrual
- Infertility (e.g., polycystic ovarian syndrome, endometriosis)
- Menopause

Miscellaneous

- Multi-system conditions (Lyme disease, chronic fatigue, fibromyalgia, temporal arteritis)



CATEGORY 2 Moderately Seen Conditions

Cardiovascular

- *Myocardial infarction
- *Angina pectoris
- *Heart failure
- *Deep vein thrombosis
- Raynaud's disease
- *Aneurysms

Dermatological conditions

- Noncontagious skin conditions (cellulitis, shingles, acne, eczema, psoriasis, alopecia)

Gastrointestinal conditions

- Peptic ulcer (e.g., H. pylori, Campylobacter)
- *Diverticular disease (e.g., diverticulosis, diverticulitis)
- Hemorrhoids
- Gallbladder conditions (e.g., cholelithiasis, cholecystitis)

Hematological conditions

- Anemia
- Bleeding disorders

Infectious Disease

- Sexually transmitted infections
- Tuberculosis

- *Viral infections (e.g., infectious mononucleosis, influenza, meningitis, conjunctivitis)

Mental and Behavioral conditions

- Attention deficit disorder (ADD)/Attention deficit hyperactivity disorder (ADHD)
- Post-traumatic stress disorder (PTSD)

Neurological conditions

- *Transient ischemic attack (TIA)
- Parkinson's disease
- *Vertigo
- Bell's palsy
- Trigeminal neuralgia
- *Concussion and traumatic brain injury (TBI)

Pulmonary conditions

- Chronic obstructive pulmonary disease

Reproductive conditions

- Uterine (fibroids and bleeding)

Miscellaneous

- Autoimmune disorders [systemic lupus erythematosus (SLE), rheumatoid arthritis (RA)]



CATEGORY 3 Least Frequently Seen Conditions

Dermatological conditions

- *Contagious skin conditions (lice, fungal infections, scabies)
- *Skin cancers (e.g., basal cell, squamous cell, melanoma)
- Burns

Endocrine and Metabolic conditions

- Adrenal disorders (e.g., Cushing's, Addison's)

Gastrointestinal conditions

- *Appendicitis
- Hepatitis
- Cirrhosis
- *Pancreatitis

Hematological conditions

- Leukemia/lymphoma
- Hemochromatosis

Infectious Disease

- *Bacterial infections (e.g., staph, MRSA, impetigo, meningitis)
- Childhood infectious conditions (measles, mumps, rubella, pertussis)
- Parasitic infections
- Foodborne illness

Mental and Behavioral conditions

- Autism spectrum
- *Suicidality
- *Eating disorders (anorexia nervosa, bulimia nervosa)

Neurological conditions

- Multiple sclerosis (MS)
- Dementia (e.g., Alzheimer's disease)
- Epilepsy

*Oncology (lung, stomach, colon, pancreas, breast, prostate, uterine, bone, liver, cervical)

Ophthalmology/ENT

Reproductive conditions

- *Complications related to pregnancy
- Breast conditions (e.g., mass, mastitis)
- Male Infertility
- Erectile dysfunction (ED)
- Prostate conditions (benign prostatic hyperplasia, prostatitis)

Urinary/Renal conditions

- *Kidney Stones
- *Infections (UTI, cystitis, pyelonephritis)
- Incontinence



The Acupuncture with Point Location Expanded Content Outline

(Effective as of February 1, 2014)

Note to Candidate: This document serves as a guide to assist in examination preparation for candidates who have met NCCAOM eligibility requirements. Below is the content outline for the Acupuncture with Point Location examination, along with the competency statements.

Please note: In regards to Clean Needle Technique (CNT), the Acupuncture with Point Location module focuses on actual needling and its emergencies (e.g., needle angle and depth) in comparison to the Biomedicine module which focuses on universal precautions and emergency situations.

DOMAIN I: Safety and Professional Responsibilities (10% of Total Exam)

Apply standards of safe practice and professional conduct.

A. Management of Acupuncture Office Emergencies

- Recognize and manage acupuncture office emergencies [e.g., moxa burns, heat lamp burns, needle shock, organ puncture, fainting, stuck needle(s)]
- Recognize the signs and or symptoms of internal hemorrhage or clotting disorders
- Recognize risk factors for individual patients (e.g., patients taking blood thinners, diabetes)

B. Infection Control/Precautions

- Recognize and apply knowledge of infection control and precautions (e.g., bloodborne pathogens, communicable diseases, universal precautions, needle stick)

C. Patient Education and Communication

- Communicate and discuss risks and benefits concerning acupuncture treatment with individual patient
- Communicate and discuss findings with individual patient
- Obtain legal informed consent
- Inform patient of initial treatment/procedure done
- Inform patient when there is a change in condition or treatment that may require a new plan of action



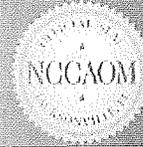
DOMAIN II: Treatment Plan (70% of Total Exam)

Develop a comprehensive treatment plan using acupuncture points based on patient presentation and initial assessment.

A. Treatment Plan: Develop an Initial Treatment Plan

1. Point selection based on differentiation and/or symptoms (35%)

- Identify pattern and develop treatment plan based on differentiation (e.g., syndrome/pattern, meridian/channel pathology, circadian rhythm)
 - a. Cautions and contraindications
 - Recognize cautions and contraindications (e.g., pregnancy, organ damage)
 - Determine appropriate points, needling methods and modalities for safe treatment
 - b. Point category
 - Demonstrate knowledge and use of Antique/Five Transporting (Shu) points (e.g., Jing-Well, Ying-Spring, Shu-Stream, Jing-River, He-Sea)
 - Demonstrate knowledge of theories and applications of source (Yuan) and connecting (Luo) points
 - Demonstrate knowledge of theories and applications of Front-Mu (Alarm) points, Back-Shu (Associated) points and their combination(s) (e.g., excess/deficient, systemic imbalances)
 - c. Channel theory
 - Demonstrate application of channel theory
 - d. Function and/or indication of points and point combinations
 - Demonstrate knowledge of functions, indications and application of points and point combinations (e.g., distal/local, Window of the Sky, Five Elements, circadian rhythms, Six Stages, Four Levels)



e. Ashi points

- Demonstrate application or the use of Ashi points (including trigger points and motor points)

f. Extra points (**Refer to Appendix of Extra Points**)

- Demonstrate the knowledge of indications and application of Extra points

g. Auricular points

- Demonstrate knowledge of functions, indications, applications, precautions and contraindications of auricular acupuncture points and anatomical areas

h. Scalp areas

- Demonstrate knowledge of functions, indications, applications, precautions and contraindications of scalp acupuncture

2. Treatment techniques and mode of administration (**25%**)

- Demonstrate knowledge of treatment techniques and modes of administration

a. Cautions and contraindications

- Recognize cautions and contraindications for individual patient
- Recognize cautions based on anatomy

b. Patient position

- Demonstrate knowledge of appropriate patient position

c. Point locating techniques

- Demonstrate knowledge of point location (e.g., anatomical landmarks, Cun measurement, palpation)

d. Needle selection

- Recognize and demonstrate knowledge of appropriate needle selection (e.g., filiform, three-edged, plum-blossom, press tack, intradermal)



- Recognize and demonstrate knowledge and appropriate use of needles (e.g., length, gauge, filiform, three-edged, plum-blossom, press tack, intradermal)

e. Needling technique

- Demonstrate knowledge of needling techniques (e.g., insertion, angle, depth, stretching skin)
- Demonstrate knowledge of needle manipulation (e.g., arrival of Qi, reinforcing, reducing, lifting and thrusting, plucking, rotating, twirling)
- Demonstrate knowledge of appropriate needle retention
- Demonstrate knowledge of safe and appropriate needle removal

f. Moxibustion

1.) Direct

- Demonstrate knowledge of functions, indications, contraindications and application of direct moxibustion (e.g., thread, cone, rice grain)

2.) Indirect

- Demonstrate knowledge of functions, indications, contraindications and application of indirect moxibustion (e.g., stick/pole, on ginger, box)

3.) On needle handle

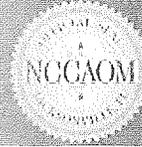
- Demonstrate knowledge of functions, indications, contraindications and application of moxibustion on needle handle

g. Additional acupuncture modalities

- Demonstrate knowledge of functions, indications, contraindications and application of other acupuncture modalities

1.) Cupping

- Demonstrate knowledge of functions, indications, contraindications and application of cupping



2.) Guasha

- Demonstrate knowledge of functions, indications, contraindications and application of Guasha

3.) Bleeding

- Demonstrate knowledge of functions, indications, contraindications and application of bleeding

4.) Intradermal needles, ear balls, seeds, pellets, tacks

- Demonstrate knowledge of functions, indications, contraindications and application of intradermal needles

5.) Electro acupuncture

- Demonstrate knowledge of functions, indications, contraindications and application of electro acupuncture

6.) Heat

- Demonstrate knowledge of functions, indications, contraindications and application of heat (e.g., TDP/heat lamp)

7.) Topical applications

- Demonstrate knowledge of functions, indications, contraindications and application of topical applications (e.g., liniment, plaster)

h. Related modalities

1.) Asian bodywork therapy and other manual therapies

- Demonstrate knowledge of indications and contraindications of Asian bodywork therapy and other manual therapies

2.) Exercise/breathing therapy

- Demonstrate knowledge of exercise/breathing therapy (e.g., Qi Gong, Tai Ji).



3.) Dietary recommendations according to Traditional Chinese Medicine theory

- Demonstrate knowledge of dietary recommendations according to Traditional Chinese Medicine theory

B. Patient Management (10%)

1. Re-assessment and modification of treatment plan

- Reevaluate and modify treatment plan (e.g., diagnostic assessment, point selection, needling technique, other modalities, treatment frequency)

2. Referral and/or discharge of patient as appropriate

- Recognize and evaluate the need for referral
- Demonstrate the knowledge of referral to other healthcare providers
- Recognize and evaluate appropriate discharge of patient

DOMAIN III: Point Identification/Location (20% of total exam)

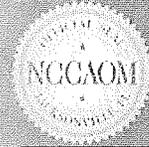
(To include both image based questions and questions describing point location measurements by description.)

A. Identification of Points by Images (10%)

- Identify by cun and anatomical landmarks

B. Identification of Points by Description (10%)

- Identify by cun and anatomical landmarks



Appendix: Extra Points

(Please Note: Additional Extra Points not listed in the Appendix may appear on the exam as distractors to the correct answer)

Anmian	Pigen
Bafeng	Qianzheng
Baichongwo	Qiduan
Bailao	Qipang
Baxie	Qiuhou
Bitong	Sanjiaojiu
Bizhong	Shanglianquan
Dagukong	Shangyingxiang
Dangyang	Shiqizhuixue/Shiqizhuixia
Dannangxue	Shixuan
Dingchuan	Sifeng
Erbai	Sishencong
Erjian	Taiyang
Haiquan	Tituo
Heding	Waihuaijian
Huanzhong	Wailaogong
Huatuojiaji	Weiguanxiashu
Jiachengjiang	Xiaogukong
Jianqian/Jianneiling	Xiyan/Neixiyan
Jingbailao	Yaotongxue
Jinjin and Yuye	Yaoyan
Juquan	Yiming
Kuangu	Yintang
Lanweixue	Yuyao
Luozhen	Zhongkui
Neihuaijian	Zhoujian
Neiyingxiang	Zigongxue



Bibliographies

In addition to the NCCAOM content outlines, the suggested bibliographies have been updated. Attached are the new bibliographies for the Certification in Acupuncture examinations. These bibliographies are effective in 2015.

Foundations of Oriental Medicine Bibliography

The Content Outline is the primary resource for studying for this examination. The purpose of this Bibliography is only to provide the candidate with suggested resources to utilize in preparation for the examination. Candidates should feel free to consider other resources that cover the material in the Content Outline.

There is no single text recommended by NCCAOM. All NCCAOM modules and examinations reflect practice in the United States as determined by the most recent job analysis.

NCCAOM's item writers and examination development committee members frequently use the following texts as resources; however, the sources used are not limited to the books listed here. The NCCAOM® does not endorse any third-party study/preparation guides.

Cheng, Xinnong, ed. *Chinese Acupuncture and Moxibustion*. 3rd ed. Beijing: Foreign Languages Press, 2010.

Clavey, Steven. *Fluid Physiology and Pathology in Traditional Chinese Medicine*. 2nd ed. Churchill Livingstone, 2003.

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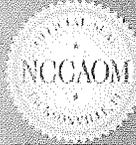
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---. *The Practice of Chinese Medicine: The Treatment of Diseases with Acupuncture and Chinese Herbs*. 2nd ed. Philadelphia: Elsevier Churchill Livingstone, 2007.

Scheid, Volker, Dan Bensky, Andrew Ellis, and Randall Barolet. *Chinese Herbal Medicine: Formulas and Strategies*. 2nd ed. Seattle, WA: Eastland Press, 2009.

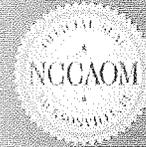


National Certification Commission
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Wiseman, Nigel, and Andy Ellis. *Fundamentals of Chinese Medicine*. Revised Edition. Brookline, MA: Paradigm Publications, 1995.

Wu, Yan, and Warren Fischer. *Practical Therapeutics of Traditional Chinese Medicine*. Ed. Jake P. Fratkin. Brookline, MA: Paradigm Publications, 1997.



Biomedicine Bibliography

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Anzaldua, David. *An Acupuncturist's Guide to Medical Red Flags & Referrals*. Boulder, CO: Blue Poppy Enterprises, Inc., 2010.

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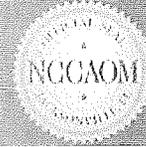


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Acupuncture with Point Location Bibliography

The Content Outline is the primary resource for studying for this examination. The purpose of this Bibliography is only to provide the candidate with suggested resources to utilize in preparation for the examination. Candidates should feel free to consider other resources that cover the material in the Content Outline.

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NCCAOM's item writers and examination development committee members frequently use the following texts as resources; however, the sources used are not limited to the books listed here. The NCCAOM® does not endorse any third-party study/preparation guides.

Primary Sources

Cheng, Xinnong, ed. *Chinese Acupuncture and Moxibustion*. 3rd ed. Beijing: Foreign Languages Press, 2010.

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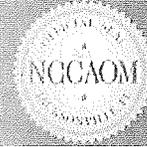
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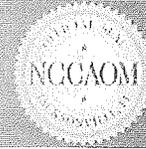


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Zhang, Ting Liang, and Bob Flaws. Trns. *A Handbook of Traditional Chinese Gynecology.* 3rd
ed. Boulder, CO: Blue Poppy Press, 1987.



Examination Nomenclature Cross-Reference

There are differences in the English language literature regarding pulses and other terminology in Oriental medicine. A cross-reference of terms that are frequently used in English language literature is provided below to assist you; however, this list is not intended to be all-inclusive. It is also provided in the form of a glossary in the English language version of Foundations of Oriental Medicine, Acupuncture, and Chinese Herbology modules/examinations. The official reference for the names of typical pulses is referenced in *The Web That Has No Weaver*.¹

1. Theory

Wu Xing = Five Phases = Five Elements
Sheng Cycle = interpromoting cycle = generation cycle
Ke Cycle = Ko Cycle = interacting cycle = control cycle
Qi = Chi = Ki = energy

2. Physiology

Qi = Chi = Ki = (vital) energy
Yuan Qi = primary Qi = original energy
Zong Qi = pectoral Qi
Ying Qi = nourishing energy
Wei Qi = protective (defensive) energy
Jing = essence
Shen = spirit
Xue = Blood
Jin Ye = Ching Ye = body fluids
Zang Fu = the organs = Yin and Yang organs
Zang = viscera = Yin organs
Fu = bowels = Yang organs

3. Pathology and Diagnosis

Xu = deficient = empty
Shi = Shih = excess = full
Sheng Cycle = Overacting = excessive action on the interacting (Ke) Cycle
Wu Cycle = Counteracting = insult cycle
Nei Yin = Endogenous = internal factors
Wai Yin = Exogenous = external factors
Wai Xie = External pathogenic factor = outside evil
She Tai = Tongue fur = moss or coating
She Ti = Tongue proper = tongue body
She Pang Da = Flabby tongue = swollen, or enlarged tongue

Pulse locations:

Cun (tsun) = inch = distal location
Guan (Kuan) = gate/bar = middle location
Chi (chih) = cubit or foot = proximal location



4. Technique

Bu = supplement = tonify

Xie = reduce = drain = sedate = disperse

5. Channels and Points

Channels = Meridians = Jing = usually Primary channels = Main (Principal, Regular) meridians

Muscle channels = tendino-muscular meridians = Jing Jin

Divergent meridians = distinct channels = Jing Pieh

Luo = connecting channels = Collaterals

Extra channels = Miscellaneous (Odd, Curious, Extraordinary, Ancestral) meridians or vessels:

Du Mai (Mo) = Governing Vessel or Meridian or Channel = GV

Ren Mai (Mo) = Conception Vessel = CV

Dai (Tai) Mai (Mo) = Belt (Girdle) Vessel

San Jiao = Triple Warmer = Triple burning Space

Cun = tsun = inch = A.C.I.

Yuan point = source point

Luo point = connecting or Junction point = Lo point

Xi point = Cleft or Accumulating point

5 Shu points = 5 Transporting, "Antique" or "Command" points of the Primary channels =

Five Element Points:

Well = Jing = Ting

Spring = Ying = Yuong or Rong = Gushing

Stream = Shu or Yu = Transporting

River = Jing = King = Ching = Traversing

Sea = He = Ho = Uniting

Back-Shu points = Associated or Associated Effect points = A.E.P. = yu point = shu point

Front-Mu = Mo = Alarm point = Bo

Reinforcing point = (mother point) = tonification point

Reducing point = (son point) = sedation, dispersing or draining point

Confluent points = Master (and coupled) or Key or Opening points of the Eight Extra Channels

Coalescent points = points of intersection between two or more channels = Crossing or Intersection points

Influential points = Eight Meeting (or Assembling) points of Energy, Blood and certain organs and tissues

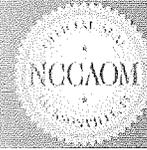
Remote points = distal points

Zi Wu Liu Zhu = Horary Cycle = 24 hour circulation of energy through the channels =

midday/midnight cycle = organ clock

Reference:

1. Kaptchuk, Ted. J. *The Web that Has No Weaver: Understanding Chinese Medicine*. McGraw-Hill Professional, 2000.



The Official NCCAOM® Online Practice Tests

The NCCAOM offers the following online practice tests subscriptions:

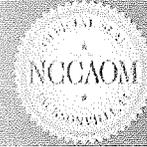
- Acupuncture
- Chinese Herbology
- Foundations of Oriental Medicine
- Comprehensive for Oriental Medicine
- Comprehensive for Acupuncture

The Acupuncture, Chinese Herbology, and Foundations of Oriental Medicine *Online Practice Tests* each contain five (5) individual practice tests consisting of 50 multiple-choice questions specifically for the practice examination. **The Acupuncture Online Practice Test does not contain any point location images; however, the Comprehensive Online Practice Test for Oriental Medicine and the Comprehensive Online Practice Test for Acupuncture both contain biomedicine questions.** The Comprehensive Online Practice Tests, each contain five (5) individual practice tests consisting of 50 multiple choice questions which have a combination of Foundations, Acupuncture, Biomedicine, and Chinese Herbology questions (example: Practice Test 1 may have 15 Foundations items, 15 Acupuncture items, 10 Biomedicine items, and 10 Chinese Herbs items and Practice Test 2 may have 10 Foundations items, 10 Acupuncture items, 15 Biomedicine, and 15 Chinese herbs, etc.).

All of the online practice test subscriptions are valid for 90 days of unlimited use.

The practice tests are designed to demonstrate the format of the questions included in the exam, but do not reflect the current exam content outlines. The practice tests are a great opportunity for applicants to become familiar with NCCAOM exam format and to adjust to computerized testing. **Performance on the practice tests is not an indicator for performance on the actual exam.**

The practice test link can be found on the NCCAOM website at www.nccaom.org under the “Applicants” menu, “Exam Content” page in the “Resource Links” box on the bottom right of the page.



Sample Questions

Sample Questions for Each Examination Module

The following questions represent different types and levels of questions that may appear on the exam. These questions do not necessarily represent the level of difficulty of the examination nor do they represent the percentage of questions regarding each area. This is merely a sample of the possible format and variety of questions to assist in preparation for the exams.

Foundation of Oriental Medicine

FOM-1

According to Five Element theory, which taste, color, and organ are associated with Metal?

- (A) bitter, red, Lung
- (B) pungent, white, Lung
- (C) spicy, yellow, Spleen
- (D) sweet, yellow, Spleen

FOM-2

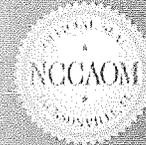
A 29-year-old woman complains of hypochondriac pain and fullness for several months. She is also experiencing dry mouth and throat, depression, moodiness, scanty menstrual flow, and breast pain. She has a pale tongue and a thready, wiry pulse. What is the most appropriate diagnosis?

- (A) Liver Fire insulting Lung
- (B) Liver Qi stagnation transforming to Fire
- (C) Liver Qi stagnation with Blood deficiency
- (D) Liver Fire attacking Stomach

FOM-3

A patient complains of shortened menstruation with scanty, dull red, clear, thin menses. She has coldness in the lower abdomen. Her tongue is pale, tender, with white fur. Her pulse is deep and tight. Which of the following is the most appropriate treatment principle?

- (A) activate the channel and clear Heat
- (B) tonify Yang and move Blood
- (C) tonify Yin and clear Heat
- (D) warm the channel and expel Cold



Biomedicine

BIO-1

A 40-year-old woman with an enlarged thyroid gland is most likely deficient in which of the following?

- (A) iodine
- (B) iron
- (C) magnesium
- (D) zinc

BIO-2

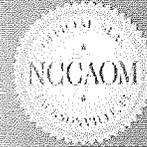
A mother reports that her active eight-year-old son has been fussy, thirsty, and tired for the past 24 hours. She also states that he complains of a headache and constipation. His blood pressure is low with a rapid pulse. Which of the following would most likely be suspected?

- (A) anxiety attack
- (B) dehydration
- (C) food poisoning
- (D) hyperthyroidism

BIO-3

A lethargic, 53-year-old male patient fell and hit his head six hours before his appointment. He now presents with confusion, difficulty remembering the event, and has vomited twice since the fall. What is the best course of action for this patient at this time?

- (A) treat him and recommend that he consult his physician
- (B) treat him and retain him in the office for observation
- (C) do not treat him, but refer him to a neurologist within 72 hours
- (D) do not treat him, but refer him immediately to the emergency department



Acupuncture with Point Location

ACPL-1

Which of the following points could be needed with the patient positioned in the prone position?

- (A) Yintang (Extra)
- (B) P 2 (Tianquan)
- (C) Sp 11 (Jimen)
- (D) GB 36 (Waiqiu)

ACPL-2

For which of the following conditions is the bleeding technique most likely indicated?

- (A) high fever
- (B) chronic asthma
- (C) anemia
- (D) diabetes

ACPL-3

Which of the following statements best describes the location of Lu 7 (Lieque)?

- (A) on the forearm, superior to the styloid process of the radius, 1 cun proximal to the transverse crease of the wrist
- (B) on the forearm, superior to the styloid process of the radius, 1.5 cun proximal to the transverse crease of the wrist
- (C) on the radial side of the flexor carpi ulnaris tendon, 1 cun proximal to the transverse crease of the wrist
- (D) on the radial side of the flexor carpi ulnaris tendon, 1.5 cun proximal to the transverse crease of the wrist

Answers:

FOM-1 = B
FOM-2 = C
FOM-3 = D

BIO-1 = A
BIO-2 = B
BIO-3 = D

ACPL-1 = D
ACPL-2 = A
ACPL-3 = B



Frequently Asked Questions

Examination Administration Frequently Asked Questions and Answers (Q&A)

In an effort to assist our candidates and school representatives to better understand our examination processes, we have created a list of questions and answers that explain in detail our examination administration policies and procedures. NCCAOM has a high level of commitment to upholding the integrity, validity and fairness of the NCCAOM certifications as meaningful measure of entry-level competency in order to protect the public. This commitment cannot be overstated; it is a requirement of our mission, which is *to establish and promote national standards of competence by utilizing evidence-based credentialing to assure the safety and well-being of the public and advance the professional practice of acupuncture and Oriental medicine.*

Question #1: When can I take the next examination as I do not see a schedule of exams on the website?

Answer: NCCAOM provides year-round testing for three of our English language certification exams, which means that “Approved to Test” candidates (who have received an authorization letter in the mail from NCCAOM) can now register for the Foundations of Oriental Medicine (FOM), Biomedicine (BIO) and Chinese Herbology (CH) NCCAOM examination(s) throughout the year, pending availability at their desired Pearson VUE Professional Test Center locations.

The Acupuncture with Point Location (ACPL) exam is offered from Monday to Saturday each week through September 30, 2015, after which it will only be offered for a two-week administration period beginning **November 9-21, 2015** and for three to four additional two week administration periods in 2016. The dates for the 2016 administration periods have yet to be determined. Watch for the 2016 ACPL test administration dates on the NCCAOM website www.nccaom.org under “What’s New” on our homepage.

For foreign language exam administrations, view Foreign Language certification exam administration and registration deadlines on the NCCAOM website [Foreign Language Exam Notification page](#).

Candidates can register for all NCCAOM examination(s) by calling Pearson VUE directly or registering online (the “Authorization to Test” letter will have detailed registration information and instructions). Candidates can register for their exams according to their own schedule and at their own convenience within the four-year open application period. NCCAOM exams are administered at over 250 Pearson VUE Professional Test Centers around the world. When candidates register, they pay Pearson VUE directly for their exams using Visa, MasterCard or American Express credit cards.



Question #2: What does open registration mean and why is there no application submission or registration deadline announcement?

Answer: Open registration means that candidates will not have to wait for the NCCAOM English Foundations of Oriental Medicine, Biomedicine and Chinese Herbology examinations to be announced (*the exception: foreign language examinations and the Acupuncture with Point Location exam module*). Once candidates are approved to test, they can register and schedule their exam for any time that is available at a Pearson VUE Professional Test Center. This means that candidates can test and be finished with the examination cycles quicker and test at a time more convenient for them.

Please remember that candidates must still allow 6-8 weeks for the processing of their application before they are approved to test. It is also important to remember that candidates have four years from the date that NCCAOM receives their application to test and become certified.

Candidates who need to retake an examination must wait **45 days** from the previous recorded test. Candidates will not be allowed to re-schedule their previously failed examination prior to the 45-day waiting period for any reason. The 45-day waiting period allows for the candidate to receive their score report (diagnostic) and review before the exam is repeated.

Question #3: Which exams are offered year-round?

Answer: The NCCAOM offers the following examinations in English throughout the year for 2015:

- Acupuncture with Point Location (*last administration for the adaptive administration on September 30, 2015*)
- Biomedicine
- Chinese Herbology
- Foundations of Oriental Medicine

The Acupuncture with Point Location (ACPL) exam module will be offered in a computer-based fixed form (linear) format on **November 9-21, 2015**.

Question #4: What about those who want to take the exam(s) in Chinese or Korean?

Answer: The foreign language examination administration will be offered:

Chinese Exams:

- June 15-27, 2015
- September 21 – October 3, 2015

Korean Exams:

- September 21 – October 3, 2015

Proposed new applicants who intend to take the NCCAOM Foreign Language Examinations (FLEs) are required to notify the NCCAOM by completing the **NCCAOM FLE Online Notification**



Form as soon as possible. The NCCAOM will use the contact information collected on this form to track the number of applicants interested in taking the FLEs. The *NCCAOM® Certification Handbook* explains the application process. View registration deadlines for the Foreign Language certification exams on the NCCAOM website [Foreign Language Exam Notification page](#).

Note: *Any foreign language examination module which does not have a sufficient number of candidates registered to take the exam over the two week examination administration period will be canceled and the testers will be refunded by Pearson VUE to the credit card on file.*

Each exam consists of 100 multiple-choice questions with a 2 ½ hour time limit. Expanded content outlines are available in Chinese or Korean on the NCCAOM website.

Question #5: Are you planning on combining any other exams or making any changes with any of the exams?

Answer: Yes. In the interest of getting more questions with updated point location images and increasing the number of updated exam items to be used for scoring on the exams, the Acupuncture with Point Location (ACPL) exam module will be administered in a computer-based fixed form (linear) format with a **November 9-21, 2015** administration and continue throughout 2016 with three to four, two week administration periods. Registration will open for the November administration period on August 1, 2015.

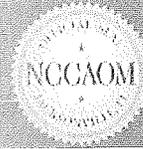
Administration of the adaptive Acupuncture with Point Location exam module will not be offered after September 30, 2015 or throughout 2016. Registration for all ACPL adaptive exam dates will close on July 31, 2015.

Question #6: What does year-round testing mean for scoring? Does this mean that I will receive my exam results faster?

Answer: Yes. Year-round testing made possible by adaptive testing (see Questions 7 and 8 for information about adaptive testing) will enable NCCAOM to provide you with immediate on screen "Preliminary Pass or Fail" status. This means that candidates will receive a **preliminary** pass/fail screen immediately after they submit their answers, while at the Pearson VUE Professional Test Center.

The **official results will be mailed within 20-30 business days** from completion of the examination. Candidates are able to request that their examination results be sent to the state licensing boards at a much quicker rate, which means that the time passed before receiving your state license will be greatly reduced.

Preliminary Pass or Fail status will not be provided for any linear exams (foreign languages and Acupuncture with Point Location exam). The official results for the Foreign Language Exams and Acupuncture with Point Location (linear format) will be mailed approximately 45 business days after the last date of the examination administration period.



Question #7: What is the format of the examinations?

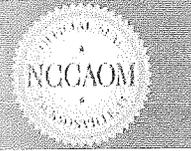
Answer: The adaptive Foundations of Oriental Medicine, Biomedicine, Acupuncture with Point Location, and Chinese Herbology examinations each have 100 multiple-choice questions with a 2 ½ hour time limit.

Adaptive Exams		
Examinations	Number of Multiple-Choice Questions	Allotted Time
Foundations of Oriental Medicine	100	2.5 hours
Biomedicine	100	2.5 hours
Acupuncture with Point Location <i>(concludes September 30, 2015)</i>	100	2.5 hours
Chinese Herbology	100	2.5 hours

In order for NCCAOM to be able to provide you with year-round testing and to provide an immediate preliminary pass/fail screen, we are offering candidates a form of testing called **adaptive testing**. What this means to the candidates is that each examination is different and is geared towards the ability of the candidate. If a question is answered correctly, the next question is slightly more difficult. If a question is answered incorrectly, the next question will be slightly easier. One feature that is required for this format is the inability to review exam questions once you have finished answering the questions. As adaptive testing measures your content knowledge with each question, you will be **unable to go back** to a question once you have moved onto the next question. Adaptive testing has been used for certification testing in other healthcare areas for more than 20 years and offers one of the most reliable measures of competency.

Starting November 2015 and throughout 2016, the Acupuncture with Point Location exam module will be offered in a computer-based fixed form (linear) format, in order to update point location images and increase the number of updated exam items to be used for scoring on the exams. The exam content will not change only the administration of the exam. In the linear format, once all items have been answered, candidates are able to review and change answers within the remaining allotted time. Preliminary pass or fail status will not be provided after the completion of the exam at the test center. Official notification letters will be mailed 30-45 business days after the completion of the examination administration period.

Linear Exam November 9-21, 2015 Administration		
Examinations	Number of Multiple-Choice Questions	Allotted Time
Acupuncture with Point Location	130	3.25 hours



Question #8: Can you explain adaptive testing in more detail and what this means to us as candidates?

Answer: An internet search will help you to find many different descriptions of Computer Adaptive Testing (CAT). The easiest explanation we have is that it is a computerized test in which the computer selects the examination questions based on the individual candidate's ability. Some have compared it to jumping a high bar – if you get over the bar, the next time the bar is higher, but if you miss, the bar is lowered. Of course, in this example, if the bar is too low you cannot pass the examination. Another analogy is to that of an interview. When someone is being interviewed, the interviewer will adjust the difficulty of the questions based on previous responses.

The objective of adaptive testing is to determine the candidate's ability with the least amount of measurement error. It is not the number of correct or incorrect questions, but the overall score based on the difficulty of the questions, the overall examination, and the ability of the candidate. From the examinee's perspective, the difficulty of the exam seems to tailor itself to their level of ability. In trying to determine the candidate's ability, the exam will continue to get more and more difficult, which can provide uniformly precise scores for most test-takers

Question #9: What are the benefits of taking the CAT or adaptive format of the exam?

Answer: There are many benefits that candidates will enjoy with adaptive and year-round testing as outlined above. These include no eligibility deadlines and final score reports can be sent, at the candidates request, to the state licensing boards much more quickly. Your examination can be scheduled at your convenience at over 250 Pearson VUE Professional Test Centers around the world; your application materials can be submitted at any time (please allow 6-8 weeks for processing); and, finally, at the end of the examination you will be able to see your preliminary pass/fail status. The most obvious benefits are that of shorter examinations and lowest possible overall costs to candidates.

Question #10: Is it true that the screen turns off after five minutes, from the time the computer is started by the proctor, if you don't answer the first question?

Answer: Yes. The first question is actually a legal agreement that says you will treat everything you read on the examination with the utmost and absolute confidentiality. If you do not agree to this agreement presented on screen within the allotted **5 minutes**, you will be logged out of the test program. In addition, you will not be allowed to continue the test and **your fees for that exam will not be refunded**. If you agree, just press **"I agree"** to start the examination. To ensure you are prepared, read the full text of the *Non-Disclosure Agreement and Full Terms of Use for the NCCAOM Exam* below:

Non-Disclosure Agreement and General Terms of Use for NCCAOM Exams

"I have read and understand the Examination Instructions. I have agreed to abide by the NCCAOM® Code of Ethics and acknowledge that if I am caught cheating on this examination, including the sharing of information after the examination is complete; I will be subject to review by the Professional Ethics and Disciplinary Committee of NCCAOM. If I am found to have



violated the Code of Ethics, I understand that my scores will be cancelled and I may not have the opportunity to test again.

Additionally, I understand that this exam is confidential and is protected by trade secret law. It is made available solely for the purpose of becoming certified by NCCAOM. I am expressly prohibited from disclosing, publishing, reproducing, or transmitting this exam, in whole or in part, in any form or by any means, verbal or written, electronic or mechanical, for any purpose.

I am the candidate whose name appears on the initial screen and as an affirmation to the Statement of Acknowledgement I signed when submitting my application. I acknowledge that I am prohibited from transmitting information about NCCAOM examination questions or content in any form to any person or entity. I also acknowledge that if I suspect a violation on the part of others, it is my responsibility to report these actions to the NCCAOM.”

Question #11: How do I prepare for an exam?

Answer: NCCAOM provides a comprehensive Study Guide for each certification program and Suggested Study Tips and Strategies for candidates preparing to take the NCCAOM exam(s). In addition, each content outline is offered separately for those who would like to go directly to the individual exam content outline. NCCAOM also offers online practice tests for a small fee, which are designed to demonstrate the format of the questions included on the exam but do not reflect the current exam content outlines. The practice tests are a great opportunity for candidates to become familiar with the NCCAOM examination format and to adjust to computerized testing. *Performance on the practice tests is not an indicator for performance on the actual exam.*

Question #12: Does the NCCAOM publish a list of formulas that will be tested in the Chinese Herbology examination?

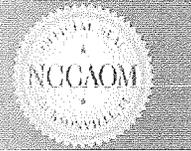
Answer: Yes. A list of formulas is made available with the Chinese Herbology content outline on the NCCAOM website. A list of single herbs is not available.

Question #13: Does the NCCAOM publish a list of the terminology for the channels and other terms?

Answer: Yes. The NCCAOM currently provides a nomenclature list, which is a cross-reference of terms that are frequently used in the English language literature. This nomenclature list is available in each of the NCCAOM® Study Guides.

Question #14: I am not certain what is covered in the Foundations of Oriental Medicine Examination compared to the Acupuncture with Point Location Examination, is there something I can review?

Answer: Please refer to the NCCAOM Study Guides or Content Outlines, which can be accessed through the NCCAOM website, www.nccaom.org under the Exam Content section or



click on the "Forms" tab. Each exam module has an expanded and abbreviated content outline in English, Chinese, or Korean.

Question #15: Do I have to answer all of the questions on the exam or can I leave some answers blank?

Answer: You must answer all of the questions on the exam in order for your examination to be scored. Adaptive testing does not allow the tester to **go back** to a question once they have moved onto the next question. Linear format testing allows the tester to go back and review the test questions once the exam is completed.

Question #16: How many questions do I have to answer correctly in order to pass an examination?

Answer: There is **NO predetermined** correct number of questions that have to be answered correctly in order for a candidate to pass. It is not the number of correct or incorrect questions, but the **overall score** based on the difficulty of the questions, the overall examination, and the ability of the candidate. For additional information, read [General Considerations for Setting a Passing Standard](#), and [Equating and Scaling: Assuring the Highest Level of Fairness for Examination Programs](#).

Question #17: If I fail the exam, can I immediately sign up for the exam again?

Answer: No. Candidates who need to retake an NCCAOM examination must wait 45 days from the previous recorded test. Candidates will not be allowed to reschedule their examination prior to the 45 day-waiting period for any reason.

NCCAOM recommends that you give yourself sufficient time to prepare for the retake of the examination that you failed. NCCAOM strongly encourages any candidate who fails an examination to seek additional study help. Speak with your school program director or faculty member, or research reputable test preparation services or publications that can assist you. The [NCCAOM® Study Guides](#) which contain the expanded content outlines are valuable resources available for your use and can be found on the NCCAOM website www.nccaom.org. Also, you are only allowed a total of five (5) opportunities to take an examination.

Question #18: I failed the exam and received my results report, what areas do I need to focus on for the next examination?

Answer: Using your results report, areas where your scaled score is below 70 units (not percentages) are the areas to focus your studies as well as taking into consideration the content percentage of that section on the content outline. Please remember the scores are scaled scores, **not** percentages.



Question # 19: I failed the exam and added all my content areas together and it was higher than 70. How is the exam scored?

Answer: The scores provided in the score reports (diagnostics) are scaled scores; they are not percentages. Thereby, by adding the total scores of each section and dividing by the total number is not how the scores are calculated. An explanation of the scoring procedure performed by our psychometric vendor is included on the web site to help you understand the scoring procedure. Please refer to the NCCAOM website under the Approved Candidate section <http://www.nccaom.org/applicants/approved-candidate>, click on the Examination Information - General section, scroll to bottom of this section to Exam Scoring Information (General Considerations for Setting a Passing Standard, and Equating and Scaling: Assuring the Highest Level of Fairness for Examination Programs).

Question #20: I failed the exam for the first time, how many candidates pass the exam during their first attempt?

Answer: Please refer to the pass rate comparison report for 2009-2014 below.

Pass Rate: First Time Test Takes for 2009 to 2014

Exam Modules	2009	2010	2011	2012	2013	2014
AC/APLA**	86.2	85.7	86.5	85.5	85.7	82.5
BIO	91.1	75.2	79.6	86.6	91.9	74.1
CH	80.1	80.6	81.2	78.2	79.8	80.0
FOM	95.0	94.8	92.8	92.7	91.8	83.8

** Acupuncture and Point Location were combined into one examination in 2008

Question #21: Is there a limit as to how many times I can take an exam?

Answer: Yes. Candidates are only allowed a total of five (5) opportunities to take an examination. After the fifth unsuccessful attempt to pass an NCCAOM examination (all formats and/or languages inclusive), the candidate has no subsequent opportunities to test in the particular exam.

Question #22: During my exam, I think one of the questions could have more than one correct answer, what is the procedure to have this question reviewed?

Answer: At the test center, a candidate can file an incident report regarding exam content concerns with the test proctor while the item is still fresh in one's mind. Be sure to obtain a copy of the incident report number. The incident report will be forwarded onto NCCAOM's testing staff.

Also, please refer to the Examination Content Complaint section of the NCCAOM® Certification Handbook. Candidates may submit concerns, believed errors in particular questions, or comments about specific aspects of the examination content, in writing to NCCAOM



(examcontent@thenccaom.org) within 30 days of taking the examination. Please be as specific as possible when challenging a question(s) for the committee to review.

No content of a specific question will be discussed with candidates. **The NCCAOM never releases copies of examinations or individual examination questions.** It is important to refrain from discussing content of the examination questions with anyone other than the NCCAOM Testing Department otherwise there would be a violation of the non-disclosure agreement.

Question #23: I passed an exam; can I find out what is my numeric score?

Answer: For candidates that pass an examination, NCCAOM **does not** provide a breakdown of the performance in each section nor the total score of the exam.

A diagnostic report of each exam section is only provided for candidates that do not pass an examination, in order to assist them in focusing their studies.

Question #24: I passed all the required exams, what are the next steps?

Answer: Candidates who have fulfilled all certification requirements can expect to receive a letter from NCCAOM confirming certification. If you want to verify required documents recorded with NCCAOM, please email docs@thenccaom.org with the subject line: Document Verification for LAST NAME, FIRST NAME, NCCAOM ID.

It is the candidate's responsibility to submit a request to the NCCAOM for their score reports to be sent to any regulatory agencies.

Updated: May 1, 2015

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E-Stim II, Dual Channel Milli-Amp / Micro-Current

\$89.00

ADD TO CART



Starter Kits

\$925.50

ADD TO CART

To show how easy it is to buy acupuncture needles without being an acupuncturist, I've broken the process down and taken screenshots. First, I went to integrativedryneedling.com and clicked on its "Dry Needling Supplies" tab, which brought me to www.ptunited.com/idn

\$283.50 1
ADD TO CART



Sage Bio-Hazard Container Bucket - 2 gallon (5.5" x 10" x 3.5")

\$33.25 1
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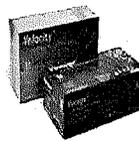
SEIRIN L-Type 0.25 x 30mm

\$7.85 1
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Starter Kit 3

\$7.00 1
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Examination Gloves Large, Nitrile (non-latex), box of 100

\$14.50 1
ADD TO CART



PT United TENS 7000 Digital Complete

\$647.50 1
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Longevity Plastic Cupping Set 16 pieces

\$10.95 1

\$39.99 1

\$45.00 1

I decided to go with the Seirin L-Type 0.25 X 30 mm for \$14.50. This is a familiar brand to me, because it is one of the best brands of acupuncture needles.

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SEIRIN L-Type 0.25 X 30mm		1	\$14.50
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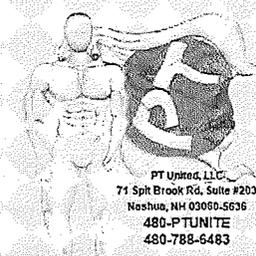
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Forgot your password?

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Checkout As Guest

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Post/Zip Code: _____

Country: United States

Additional Contact Details

Telephone: _____

Fax Number: _____

Email Address: _____

SUBMIT

As you can see, they don't require a Company name or any other credentials.

Step 1 of 3 - Shipping Information

Shipping Information:

CHANGE ADDRESS

Ashley Mayroce
4616 Western Hills Dr
West Des Moines, IA 50265-2939
United States

Your order will be shipped to the address at the left or you may change the shipping address by clicking the Change Address button.

Shipping Method:

This is currently the only shipping method available to use on this order.

Supplier Shipping	\$8.50
*Total Shipping Price:	
SERIN L-Type 1.25 x 30mm Flat Rate \$8.50	

Special Instructions or Comments About Your Order

Continue to Step 2
- choose your payment method.

CONTINUE CHECKOUT

ORDER SUMMARY

Subtotal: \$14.5

Shipping: \$8.50

Total: \$23

Customer Service

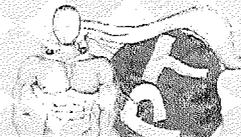
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- Massage Tools >
- Measurement >
- Modalities >
- Positioning >
- Tapes, Wraps and Sprays >
- Tables & Furniture >

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Step 3 of 3 - Order Confirmation

IMPORTANT: Your order is not complete, you must click the submit button at the bottom of this page!

Billing/Payment Information

Edit
Ashley Mayrose
4616 Western Hills Dr
West Des Moines, IA 50265-2939
United States

Delivery/Shipping Information

Edit
Ashley Mayrose
4616 Western Hills Dr
West Des Moines, IA 50265-2939
United States

Payment Method:

Credit Card

Credit Card Type:
Visa
Cardholder Name:
Ashley Mayrose
Credit Card Number:
4640XXXXXXXX2873
Expiry Date:
June, 2017

Location where you were treated.

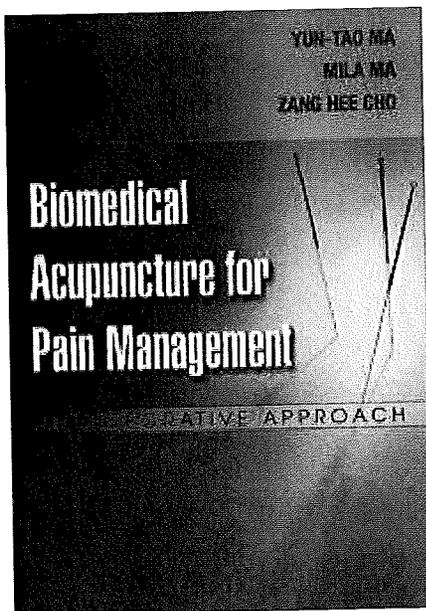
Edit
Integrative Dry Needling Institute LLC,Solon,OH

Final Step
- continue to confirm your order. Thank you!



Order Confirmation--you have to indicate "Where you were treated" in order to buy the needles, but the only option is "Integrative Dry Needling Institute LLC, Solon, OH."

Books



Biomedical Acupuncture for Pain Management

Integrative Approach, Yun-tao Ma, Mila Ma, Z.H.Cho, Elsevier, 2005

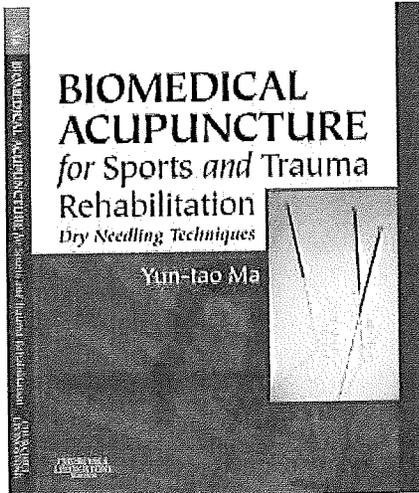
Biomedical acupuncture for pain management presents a new and unique needling system that will enable healthcare professionals in a variety of disciplines to learn and practice needling within the familiar framework of biomedical principles.

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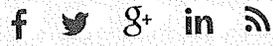
Biomedical Acupuncture for Sports and Sports Rehabilitation

Dry Needling Techniques, Yun-tao Ma, Elsevier, 2010

Biomedical acupuncture for sports and trauma rehabilitation shows techniques that will enhance athletic performance, accelerate recovery after intensive workouts, and speed trauma rehabilitation after injuries or surgeries. Evidence-based research is used to support the best and most effective techniques, with over 100 illustrations showing anatomy, injury, and clinical procedures. Unlike many other acupuncture books, this book uses a Western approach to make it easier to understand rationales and master techniques, and to integrate biomedical acupuncture into your practice. More details...

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The following information is based on a paper that Council President Lixin Huang presented at the Second International Congress of Chinese Medicine in Paris (Sept. 30-Oct. 2, 2005). The information has been revised from the original paper to reflect more recent developments and is reprinted here with the permission of the organizers of the congress.

ACUPUNCTURE AND ORIENTAL MEDICINE IN THE UNITED STATES

Focus of Paper. This paper is an overview of acupuncture and Oriental medicine (AOM) in the U.S., with particular reference to AOM education and the Council of Colleges of Acupuncture and Oriental Medicine (Council).

History in the U.S. Interest in acupuncture in the U.S. was heightened in the early 1970's when a newspaper columnist for the *N.Y. Times* newspaper (James Reston) wrote an article about the benefits of acupuncture he received while recovering from an appendectomy in China when former President Nixon made his historic visit to that country in 1972. Most of the acupuncture organizations in the U.S. began to form in the early 1980s and their collective effort at that time was to build a credible field in the U.S. for acupuncture. Except on the west coast of the U.S., the initial educational focus was specifically on acupuncture rather than the broader discipline of Oriental medicine (which includes both acupuncture and Chinese herbology). This emphasis occurred because acupuncture was first presented for consideration at that time. It was only later that acupuncture colleges began to include a Chinese herbal curriculum in their academic programs. The first acupuncture school in the U.S. was established in 1975.

Heightened Interest in Recent Years. Since the early 1990s, the AOM field has received significant national attention. Among the events that have stimulated both professional and public interest in the profession are the following:

- a television documentary and companion book in 1993 entitled "Healing and the Mind" by prominent American journalist Bill Moyers
- national surveys beginning in 1993 showing significant use by the American public of complementary and alternative medicine (CAM), including acupuncture
- regulatory action of the Food and Drug Administration in 1996 reclassifying acupuncture needles from the category of "investigational devices" subject to cautionary labeling to the category of devices that are safe and effective
- a Consensus Statement of the National Institutes of Health in 1997 affirming the value of acupuncture for treating a variety of conditions, such as nausea associated with chemotherapy and anesthesia, acute dental pain, headaches, temporomandibular joint dysfunction, fibromyalgia, and depression
- creation of the Office of Alternative Medicine (currently the National Center for Complementary and Integrative Health (NCCIH) in the

- National Institutes of Health in 1991 to foster research and research training involving CAM (including acupuncture)
- a report concerning CAM (including acupuncture) by a Presidential (White House) Commission on Complementary and Alternative Medicine Policy in 2002
 - reports referencing acupuncture by the Institute of Medicine of the National Academy of Sciences in 2004 regarding CAM in the U.S. and in 2009 concerning integrative medicine and the health of the public

CCAOM. The Council of Colleges of Acupuncture and Oriental Medicine was established in 1982.¹ The Council is the national nonprofit membership association for accredited and pre-accredited (candidate) AOM colleges in the U.S. Initially, there were very few colleges that comprised the membership of the Council, less than 12 in all. Today the Council's membership comprises 54 colleges and programs, a number of which have branch campuses. Virtually all of the AOM colleges in the U.S. that have received national accreditation are part of the Council's membership. There are around 7,771 students enrolled in the various AOM colleges. Students come to the Council's colleges from all walks of life. While in the early years students were primarily pursuing a second career, increasingly today students view this field as a first career. There is also significant academic diversity among the Council's member colleges in that there is representation for the Chinese, Japanese, Five Element, Korean, and Vietnamese traditions.

Mission and Goals of CCAOM. The mission of the Council is to support member institutions to deliver educational excellence and quality patient care. In support of this mission, the Council has the following specific organizational goals:

- to support the development and improvement of educational programs in AOM
- to develop recommended curricula for degree, diploma, and other educational programs
- to support and foster academic freedom and a diversity of educational approaches within the field
- to encourage scientific research, innovative teaching methodology, and faculty development
- to provide a forum for discussion of issues relevant to member colleges
- to serve as an information resource for member colleges, other colleges and organizations, regulatory agencies, and the public
- to encourage ethical business practices among member colleges
- to work with accreditation, certification, licensing and regulatory agencies to develop appropriate educational standards and requirements

¹ The Council was originally known as the National Council of Acupuncture Schools and Colleges. In 1993 the Council changed its name to its current title.

- to promote increased public access to high quality health care provided by well trained practitioners of acupuncture and Oriental medicine
- to take a leadership role in acupuncture safety through publication, education, and certification of a national standard for clean needle technique.

Strategic Plan. The Council's Strategic Plan provides an important operational focus for much of the organization's activities. The plan is developed directly by the Council's member colleges under professional facilitation and regularly revised and updated at national meetings. The major goals of the plan have varied over the years and the following are illustrative:

- working with other national AOM organizations to advance AOM
- reviewing and implementing a position on entry-level standards for acupuncture and for Oriental medicine
- serving as a resource for academic innovation, freedom, and excellence
- taking strong leadership in improving and promoting education in national needle safety standards and AOM safety
- enhancing graduate success
- promoting the effective use of technology in AOM education
- enhancing faculty development and student learning
- providing leadership on issues that impact AOM educational programs
- enhancing and developing AOM degree and diploma programs
- increasing the effectiveness and efficiency of Council operations
- providing for the long-term financial stability of the Council
- supporting the Council's member institutions
- increasing the visibility of the Council as a national leader in the AOM profession
- supporting the advancement and integration of the AOM profession within U.S. healthcare

Executive Committee and Staff. There are nine members on the Council's Executive Committee: President, Vice-President, Treasurer, Secretary, and four Members-at-Large. If not term limited, the Immediate Past President is also part of the Executive Committee. These officers are all full-time Presidents, CEOs, AOM Program Directors, or top administrators at the Council's member colleges and serve 2-year terms with a right of re-election subject to term limits. Between the Council's biannual meetings, the Executive Committee is charged with the management of the Council's affairs. There are two full-time staff positions with the Council—an Executive Director and a Clean Needle Technique Program Manager/Finance Administrator. The Council's national office has been located in Baltimore, MD since 2009.

Council Committees. The Council has numerous committees whose members comprise key administrative and academic officials at its member colleges. The work of these committees touches many subject areas, such as accreditation, bylaws, clean needle technique, curriculum development, distance education, ethics, finance, first-professional doctorate, Chinese herbs, legislation, AOM libraries, marketing and public relations, membership, faculty development, nominations, research, student affairs, and school clinics.² Because the membership of the committees is geographically dispersed throughout the U.S. where the Council's member colleges are located, the work of the committees, including that of the Executive Committee, is largely accomplished through e-mail, internal web platforms, and conference calls. Active committees usually meet face-to-face at the Council's biannual meetings. Exceptionally, a committee may also meet face-to-face between meetings when charged with a special project.

National Needle Safety Program. The Council administers a national needle safety program for new AOM graduates known as the Clean Needle Technique (CNT) course. This one-day course is offered approximately 50 times each year in the U.S. and consists of a didactic portion, a supervised practical demonstration of the knowledge and skill required for the safe use of acupuncture needles, and a written examination. The basis of the course is the *Clean Needle Technique (CNT) Manual—Best Practices for Acupuncture Needle Safety and Related Techniques* (7th ed. 2015).³ The course is taught by approximately 30 specially trained CNT instructors who are licensed acupuncturists and NCCAOM Diplomates, and who receive annual evaluations and periodic re-trainings. Each year approximately 2000 applicants take this course, successful completion of which is required by NCCAOM for a person to obtain national certification in acupuncture. In recent years, the Council has offered the course in China and Korea. The national standard represented by the Council's CNT course provides a necessary verification of the competency of AOM students and graduates in their safe use of acupuncture needles. Through this state-of-the-art needle safety program, the Council and its Clean Needle Technique Committee play a key leadership role in promoting safety in the practice of AOM.

National Meetings. The full Council meets twice each year, once in the spring and again in the fall. Both meetings provide a valuable forum for the Council's member colleges to discuss issues of common interest in committee and plenary sessions and to attend member training workshops and panel presentations sponsored by the Council. The national accrediting organization for the profession (ACAOM) often provides specialized workshops at the meetings for Council members concerning the accreditation process. In recent years, the biannual meetings have also provided an opportunity for visits to one or more of the Council's member colleges that may be located near the conference venue.

² A list of all committees may be viewed at <http://www.ccaom.org/committees.asp>.

³ The CNT Manual may be viewed at <http://www.ccaom.org/cntmanual.asp>.

Off-Site Clinics. The Council's member colleges are very active in providing AOM services and student internships through off-site clinics in communities where the colleges are located. The colleges provide these services in well over 100 such clinics and in a variety of health care settings including: hospitals; multi-specialty centers; research-based centers; long and short-term rehabilitation centers; family practice clinics; nursing homes; out-patient geriatric/assisted living centers for seniors; drug treatment centers; HIV/AIDS treatment facilities; pediatric, cancer, and other specialty care centers; clinics addressing specific community group needs, such as women's health and inner city/low income/multi-racial groups; and sports medicine clinics.

Publications. The Council publishes an annual newsletter at the end of each year (*CCAOM News*), a general informational brochure about the Council as an organization, and a career brochure for potential AOM students (*Choose a Fulfilling Career in Acupuncture and Oriental Medicine*). The Council's website (www.ccaom.org) contains general information about the Council and serves as a resource for member colleges, AOM students, career counselors, patients, and practitioners. An informative chart on the website ("Know Your Acupuncturist") compares the varying levels of training that a comprehensively trained professional acupuncturist receives specifically in acupuncture versus that received by other health care providers who may use acupuncture in their practice.⁴

Collaboration with Other National AOM Organizations. The Council works closely with other AOM organizations to promote national standards of education and training, including national standards of needle safety. At the initiative of the Council, eight major AOM organizations in the U.S. have been meeting annually since 2005 to discuss issues and topics of common interest. For the Council, these meetings have been valuable in informing the Council's own strategic planning. For all organizations, the meeting is intended to provide an opportunity to enhance their inter-organizational communications and working relationships for the benefit of the AOM profession.

AOM Day. Since 2002 AOM national organizations in the U.S. have promoted October 24 as National Acupuncture and Oriental Medicine Day. This effort is designed to increase the visibility of AOM in the U.S. On this day, the Council's member colleges may issue local press releases or engage in other media outreach and special activities at their institutions to commemorate the day, encourage local governments where the colleges are located to issue a proclamation concerning the day, provide free or significantly discounted treatments in college clinics, conduct "open house" visits to the colleges for the public, offer public lectures on AOM at the colleges or in local communities, conduct *Tai qi* or *Qigong* demonstrations, and provide notices to alumni urging them to offer free treatments or talks at their private clinics. This day is also commemorated in several other countries, such as Canada, Mexico, and Pakistan.

⁴ This chart may be viewed at http://www.ccaom.org/downloads/CCAOM_KnowYourAcu.pdf.

ACAOM. When the AOM profession was being organized in the U.S., the AOM educational community realized that it needed a separate and independent accreditation commission recognized by the U.S. Department of Education. Accordingly, the Council, along with the former American Association of Oriental Association (AAOM), assisted in the formation of the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) in 1982.⁵ The U.S. Department of Education currently recognizes ACAOM as a specialized and professional accrediting agency for AOM. ACAOM is the only organization in the U.S. that has federal authority to accredit AOM colleges and programs. The primary purpose of ACAOM is to establish comprehensive educational and institutional requirements for AOM programs in the U.S., and to accredit programs and institutions that meet these requirements. The establishment of ACAOM and its recognition by the U.S. Department of Education has made it possible for AOM students to obtain federal student loans for their education. Current accreditation standards, as well as the policies and procedures of ACAOM, may be viewed at www.acaom.org.

NCCAOM. In 1982 the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) was also created.⁶ Its mission is to assure the safety and well-being of the public and to advance the professional practice of AOM by establishing and promoting national evidence-based standards of competence and credentialing. NCCAOM is the only national examining body in the U.S. for the AOM field and its certification programs are accredited by the National Commission for Certifying Agencies (NCCA). The NCCAOM administers national examinations in the fields of acupuncture, Chinese herbology, and Oriental Medicine. Since its inception in 1982, NCCAOM has certified over 21,000 Diplomates in these subject areas (including Asian Bodywork Therapy). Most states that regulate AOM by statute accept or require the national certification examinations of NCCAOM in connection with the state licensure of AOM practitioners. Additional information concerning NCCAOM may be viewed at www.nccaom.org.

AAAOM. Before 2007, there were two national professional associations of AOM practitioners in the U.S.--the American Association of Oriental Medicine (AAOM), which was formed in 1982, and the Acupuncture and Oriental Medicine Alliance (AOMAlliance), established in 1994. In 2007, these two organizations merged into the American Association of Acupuncture and Oriental Medicine (AAAOM) whose mission is to support its members and the AOM community through education, occupational resources, media support, and legislative advocacy to facilitate access to the highest quality of healthcare in the U.S. There is also an American Society of Acupuncturists (ASA), which is an umbrella organization for state AOM associations. In addition to their other activities, AAAOM and ASA take

⁵ ACAOM was originally known as the National Accreditation Commission for Schools and Colleges of Acupuncture and Oriental Medicine (NACSCAOM).

⁶ The original name for NCCAOM was the National Commission for the Certification of Acupuncturists (NCCA).

a leadership role for the profession in promoting the practice rights of AOM practitioners at the federal and state levels.

Other Major AOM Associations. Some other AOM organizations that exist in the U.S. include the following:

- American Organization for the Bodywork Therapies of Asia (AOBTA) (<http://www.aobta.org>)
- International Veterinary Acupuncture Society (IVAS) (<http://www.ivas.org>)
- National Acupuncture Detoxification Association (NADA) (<http://www.acudetox.com>)
- Society for Acupuncture Research (SAR) (<http://www.acupunctureresearch.org>)
- Acupuncturists Without Borders (AWB) (<http://www.acuwithoutborders.org>)
- National Federation of Chinese Traditional Chinese Medicine Organizations (NFCTCMO) (<http://www.nfctcmo.org>)

Participation in National CAM Meetings. In addition to its interaction with other national AOM organizations, the Council also participates in meetings with other entities whose activities affect the broader field of complementary and alternative medicine (CAM) in the U.S. For example, the Council was represented at the meetings of the Institute of Medicine of the National Academy of Sciences in 2003-2004 concerning scientific, policy, and practice questions associated with the increasing use of CAM therapies by the American public. The Council is currently represented on the Academic Consortium for Complementary and Alternative Health Care (ACCAHC), an organization that consists of the national accreditation, certification, and college membership organizations for the five licensed CAM professions of AOM, chiropractic, naturopathy, massage therapy, and direct-entry midwifery. The mission of ACCAHC is to enhance health by cultivating partnerships and advancing interprofessional education and collaborative practice. See www.accahc.org.

Membership in NAAHP. Beginning in 2006, the Council has been active as a patron member in attending the biennial meetings of the National Association of Advisors for the Health Professions (NAAHP), an association of over 1000 health professions advisors at colleges and universities throughout the U.S. Participation in the activities of NAAHP was mandated in a number of the Council's strategic plans from 2006-2009. In 2010 the Council became a member of NAAHP's Advisory Council, which serves as the linking body between the health profession advisor members of NAAHP, the NAAHP board, and the health professions. NAAHP also designated a special liaison to the Council in 2010. A number of the Council's member colleges have also become patron members of NAAHP to take advantage of the opportunity membership provides to educate this key constituency about careers in the AOM profession. See www.naahp.org.

International Activities. The Council was represented at the EUROTCM meeting in Vienna in 2002, the International Congress of Chinese Medicine in Paris in 2005, and has been regularly represented by its president at meetings of the World Federation of Chinese Medical Societies (WFCMS). In 2010, the Council was represented at the meeting of the Traditional Chinese Medicine technical committee of the International Standards Organization (ISO) in Beijing. The Council is also a member of the International Tiger Coalition, an alliance of organizations with the aim of bringing back wild tigers by stopping trade in tiger parts and products from all sources (*see* <http://bigcatrescue.org/international-tiger-coalition>).

Practice Rights for Acupuncture. Currently the right to practice acupuncture by statute exists in 45 states and in the District of Columbia. The right to practice may be designated by licensure, certification, or registration under state law, although licensure is the most common form of authorization to practice. There are approximately 30,000 AOM practitioners in the U.S. with a substantial number located in California, New York, and Florida.

The authority to practice is a state process in the U.S. because the regulation of the health professions is principally in the legal domain of the states, not the federal government. Most states adopted acupuncture laws in the 1970s and 1980s. In the few states that have not yet adopted acupuncture practice statutes, the right to practice this profession may be limited to designated medical providers or to professional acupuncturists who are medically supervised. Most states follow the current trend of licensing AOM practitioners as independent providers of health care.

The various state statutes regulating the scope of acupuncture practice are not uniform, a fact that has inhibited full interstate reciprocity for practitioners. In some jurisdictions there are very detailed statutes and regulations, but this is not true of all states. Some states reference the right to practice acupuncture only, with other states recognizing such forms of Oriental medicine practice as herbs and Oriental bodywork, as well as a wide range of adjunctive therapies.

The administrative structure for the regulation of acupuncture in the states varies considerably. For example, there may be an independent board composed of comprehensively trained professional acupuncturists, or the profession may be regulated by a state medical board with the assistance of an advisory acupuncture board or committee. This diversity in legal regulation at the state level is likely to continue in the future as each state tailors its law to meet local needs and budgetary requirements.

The Council periodically communicates with legislative and regulatory bodies in the states to urge the adoption of national standards of education, training, and certification for AOM. The Council believes that adherence to the national standards of education and training of ACAOM, passage of the national certification examinations of NCCAOM, and completion of the Council's national

needle safety course (CNT course), promote a high level of practitioner competence and safety, and a degree of uniformity that facilitates reciprocity among the various states in the recognition of practitioner credentials.

Academic Training. For some time in the U.S. there has been a significant and sometimes contentious discussion concerning the amount of academic training a person needs to practice AOM at the entry-level and what the most appropriate professional title should be for providers. At a national meeting of AOM professional and educational communities in Elk Grove, Illinois in 1985, it was decided that AOM educational institutions and the profession itself were not then sufficiently mature to warrant doctoral-level education as the entry-level standard. Accordingly, it was decided that the Master's degree and Masters-level education should be the entry-level standard for the profession.

ACAOM, the national accrediting organization for the profession, mandates a minimum of 1,905 curriculum hours over a three-year period for the study of *acupuncture*. This consists of at least 705 didactic hours in Oriental medical theory, diagnosis, and treatment techniques in acupuncture and related studies; 660 hours in clinical training; 450 hours in biomedical clinical sciences; and 90 hours in counseling, communication, ethics, and practice management. For the study of *Oriental medicine*, ACAOM requires a minimum of 2,625 curriculum hours over a four-year period that includes at least 705 hours in Oriental medical theory, diagnosis, and treatment techniques in acupuncture and related studies; 450 hours in didactic Oriental herbal studies; 870 hours in integrated acupuncture and herbal clinical training; 510 hours in biomedical clinical sciences; and 90 hours in counseling, communication, ethics, and practice management.

The amount of education and training that a professional acupuncturist receives in acupuncture in the U.S. significantly exceeds that received by other health care providers who have not completed an ACAOM-approved AOM program, but who may use acupuncture as part of their primary practice. As evident from the curriculum hours specified above for ACAOM-approved acupuncture programs, a professionally trained acupuncturist must receive a minimum of 1,365 hours of training specifically in acupuncture (i.e., 705 hours didactic hours in Oriental medical theory, diagnosis, and treatment techniques in acupuncture and related studies, and 660 hours in clinical training). The actual amount of training in acupuncture at ACAOM approved programs exceeds this minimum. Other health care providers, such as medical doctors, osteopaths, naturopaths, chiropractors, or physical therapists typically receive 300 hours or less of training specifically in acupuncture. The Council recommends that any health care provider who wishes to provide acupuncture should receive comprehensive training in acupuncture at an ACAOM-approved program. For a comparison of the levels of training a comprehensively trained acupuncturist receives in acupuncture compared to that of other health care providers who may use acupuncture in their practices, see http://www.ccaom.org/downloads/CCAOM_KnowYourAcu.pdf.

Masters Degrees. There are currently two types of Master's degrees accredited by ACAOM: (1) the Masters in Acupuncture, which is a 3-year resident program of a minimum of 1,905 hours; and (2) the Masters in Oriental Medicine, which is a 4-year resident program of a minimum of 2,625 hours. Oriental medicine programs include the study of both acupuncture and Chinese herbology. These are minimum academic hourly requirements. In practice, the average number of academic hours of study and training associated with the Masters Degrees among AOM colleges nationally is between 2,600-2,800 hours. Moreover, a significant number of colleges have a curriculum of 3,000 hours or more. The trend over the years has been for an increase in the number of academic hours. A number of colleges offer a separate acupuncture only program. For years the Council worked through its Curriculum Development Committee in making recommendations to ACAOM for refining and improving the content of these two Master's degrees.

Professional Titles. In most states, AOM practitioners are designated "licensed acupuncturists," but in some jurisdictions they may be designated "acupuncture physicians" or "doctors of Oriental medicine." These doctoral designations, however, are *licensure titles* conferred by the state and do not reflect earned academic degrees at the doctoral level.

Masters Standards Task Force. Beginning in 2008, the Council, along with other organizations that comprise ACAOM's major AOM communities of interest, participated in the work of a Masters Standards Task Force convened by ACAOM to re-conceptualize accreditation standards for the Master's degree. The re-conceptualization is intended to reflect the approach taken in ACAOM's recent draft standards for a first-professional doctoral degree (see discussion below), which focuses more on the assessment of institutional, program, and student learning outcomes rather than the process and inputs-based approach reflected in many of the current Master's degree standards. In addition, the new re-conceptualized Masters standards will include provisions for assessing distance learning modes of program delivery. To date, the Task Force has developed four drafts of re-conceptualized standards and ACAOM has solicited public comment and held one public hearing concerning the standards. It is expected that in the near future the Task Force will review all public comments and develop a final draft of the standards for additional public comment.

Doctorate in Acupuncture and Oriental Medicine. In the 1990s, the Council began to work on a credible post-graduate clinical doctoral degree with a focus on specialization and advanced knowledge and skills. In 2002 ACAOM approved the first doctoral programs in AOM based on curriculum that had been developed by the Council. The new degree is known as the Doctorate in Acupuncture and Oriental Medicine (D.A.O.M). A number of the Council's member colleges have been either accredited or granted pre-accreditation (accreditation candidacy) status by ACAOM to offer this degree, which must be a minimum of 1200 hours of advanced training at the doctoral level and completed within four calendar years from the date of matriculation. Under ACAOM's present standards, a Master of

Oriental Medicine (M.O.M.) degree with a Chinese herbal medicine curriculum is a prerequisite for doctoral training. In 2014, however, ACAOM is considering proposed revisions to its standards that would allow approved programs to offer post-graduate doctoral training that does not include herbal medicine training or a M.O.M. degree as a prerequisite. ACAOM's proposed revisions may be viewed at <http://www.acaom.org/documents/file/draft-revisions-to-acaom-postgraduate-doctoral-standards-3.14.pdf>.

First-Professional Entry-Level Doctorate. A first-professional, entry-level doctoral degree, which does not yet exist in the AOM profession, should be distinguished from the post-graduate clinical Doctorate in Acupuncture in Oriental Medicine (D.A.O.M.) degree that ACAOM has already approved for qualifying AOM institutions. The latter degree is not intended to be an entry-level degree.

In the fall of 2002 ACAOM conducted a survey of its communities of interest to determine whether there was sufficient support to develop first-professional doctoral standards. The results of the survey showed that respondents were evenly divided on this issue. In light of this development and the possibility that the profession might migrate to an entry-level doctorate, early in 2003 the Council established an Entry-Level Standards Committee (currently the First Professional Doctorate Committee). The charge of the committee was to develop and implement a plan for soliciting proposals concerning possible changes in entry-level to the profession of independent Oriental Medicine Provider and independent Acupuncture Provider (for example, 10/15 years respectively for a doctorate). To enable all the colleges to participate fully and openly in this process, the Council reaffirmed its support for the Master's degree as the entry-level standard during this process.⁷

In 2003 ACAOM established a Doctoral Task Force charged with developing a list of professional competencies that might be expected of the graduates of entry-level, first-professional doctoral programs in the U.S. Along with a number of other national AOM organizations comprising a cross-section of ACAOM's major communities of interest, the Council participated from 2004-2005 in meetings of the Task Force. The Council's Core Curriculum Committee (currently the Curriculum Development Committee) performed very significant work in assisting the Task Force in identifying the first-professional doctoral competencies. In 2005 the Task Force issued a report concerning the competencies. The report was designed to form the basis for the development of accreditation standards for first-professional doctoral programs. ACAOM then initiated a period of public comment and hearings concerning the report. In 2007 ACAOM re-convened the Task Force so that its communities of interest could participate directly in the development of

⁷ The subsequent report of the Council's Entry-Level Standards Committee, based upon its call for position papers relating to entry-level requirements, may be viewed at <http://www.ccaom.org/elsc.asp>.

accreditation standards for ACAOM's consideration. Later that same year ACAOM released the standards for public comment and held a public hearing.

In February of 2008, however, ACAOM adopted a formal resolution stating that there was insufficient evidence of consensus within its AOM communities of interest to warrant implementation of a first-professional doctorate as entry-level into the profession. The resolution indicated that, in the absence of such consensus, ACAOM lacked authority under applicable U.S. Department of Education criteria to make decisions about whether or when the doctoral standards are adopted for purposes of entry into the profession. Accordingly, the resolution urged ACAOM's communities of interest to continue to seek consensus by appropriate means and stated that once consensus was reached, ACAOM would renew its efforts to develop and pilot the standards for first-professional doctoral programs.

At its spring meeting in 2008, the Council adopted a formal resolution supporting the offering of first-professional doctoral education in Oriental medicine and in acupuncture with appropriate standards of accreditation. The resolution also stated that the Council would continue to review and forward to ACAOM recommendations regarding ACAOM's draft of first-professional doctoral standards. The resolution further affirmed the Council's commitment to providing resources and support to its member colleges during this period. In this regard, the Entry-Level Standards Committee (currently the First Professional Doctorate Committee) and the Core Curriculum Committee (currently the Curriculum Development Committee) were directed to take a leading role, with support from the Faculty Development Committee, the Research Information Committee (currently the Research Committee), and the Libraries Committee. The resolution envisioned that the Council would initiate a dialogue toward building consensus with members of the profession regarding issues of the first-professional doctorate and its implications for the AOM profession.

In August of 2009 and based on comments it had received from its communities of interest, ACAOM revisited its previous resolution of 2008 and decided to continue the comment period for seeking information and consensus regarding the first-professional doctorate until January 15, 2010. During this period the relevant committees of the Council completed their review of the doctoral standards and conducted a survey of the Council's member colleges regarding the first-professional doctorate. On January 12, 2010, the Council sent formal correspondence to ACAOM with recommendations regarding the standards and a statement of support for the continued development of the first-professional doctorate.

At its February 2010 meeting, ACAOM considered all the public comment it had received regarding the first-professional doctorate and announced that it was satisfied that there was sufficient support to justify further development of the standards. The Doctoral Task Force was authorized to complete its work in developing standards for accrediting first-professional doctoral programs in AOM

for ACAOM's review and consideration. ACAOM further stated that in taking this action, it was not taking a position on whether the first-professional doctorate should be a mandatory educational requirement for the professional practice of AOM, as that is the prerogative of state legislative and AOM regulatory bodies. The Task Force subsequently reconvened in 2011 and developed another draft of the doctoral standards that was the subject of public comment until May 4, 2012. Following its review of the final recommendations of the Task Force, ACAOM in February of 2013 announced its approval of FPD standards for a first professional doctorate degree in acupuncture and/or in Oriental medicine.

Colleges interested in offering the FPD degree on a pilot basis must submit a substantive change application to ACAOM for approval to offer this degree. The FPD professional competencies consist of a core set of foundational competencies, which are at the master's level and which are required of both master's and doctoral graduates, plus a supplemental set of more advanced competencies, which are at the doctoral level and are required of doctoral graduates only. The FPD degree programs must be at least four academic years in length and approved schools may offer this degree in acupuncture or in Oriental medicine. ACAOM's first-professional doctoral standards may be viewed at <http://www.acaom.org/hot-news> (see "ACAOM Approves FPD Standards").

The work of the Council concerning the first-professional doctoral degree continues, mainly through the efforts of the First Professional Doctorate Committee in providing feedback to ACAOM concerning the standards and in exploring various non-curriculum issues associated with the degree. Whether and when the first-professional doctoral degree may eventually become the entry-level requirement for the AOM profession are open questions that involve unsettled issues of professional consensus and state law.

Future of AOM in the U.S.

- It is anticipated that in the U.S. there will be more collaborative research projects involving the Council's member colleges and medical universities. The Council is very interested in promoting greater AOM research generally and in assisting its member colleges in increasing their own AOM research activities.
- The trend toward more integrated clinical and educational collaboration involving conventional medical and AOM providers seems likely to increase. Most of the medical schools in the U.S. now offer coursework on complementary and alternative medicine. Integrated clinical settings involving conventional medical and CAM practitioners hold the promise of providing patients the most effective, least costly health care options for their well-being. This may not occur as effectively where conventional and CAM practitioners function in isolation from each other. Integrated clinical settings also provide an opportunity for conventional medical practitioners to

learn more about the energetic paradigm that underlies AOM and to observe demonstrations of its efficacy in actual practice.

- **The Council has a strong interest in working internationally for academic and clinical exchange. The Council will also continue to take significant steps in enhancing the international standing not only of the Council, but also of the AOM profession in the U.S. The degree to which the profession is organized in the U.S. appears to be unique in comparison to other countries.**
- **Debate concerning the desirability of a first-professional entry-level doctorate, which has been ongoing for years, will likely continue but may be better informed over time through the work ACAOM has done in developing standards for a first-professional doctorate degree, as well as that of the Council and other AOM organizations in identifying and clarifying issues relevant to doctoral education.**
- **In general, the future of AOM in the U.S. seems promising. Increasingly, the general public and the conventional medical profession are becoming more aware that there is a dimension of health care that lies beyond the physical nature of a person and that successful well-being if not actual healing involves application of holistic perspectives and related therapies. As this awareness continues to solidify within the culture over time, and as the safety and efficacy of AOM become more widely known and accepted, AOM should be more in demand and the profession should grow and prosper in the U.S.**

THE NCCAOM
CERTIFICATION IN
ACUPUNCTURE



About Acupuncture

The practice of acupuncture in the United States incorporates medical traditions from China, Japan, Korea, and other countries. ¹ Acupuncture is one of the essential elements of Oriental medicine and the oldest, most commonly used medical procedure in the world. Originating in China more than 3,000 years ago, the practice of Oriental medicine includes acupuncture, electro-acupuncture, cupping, manual therapies such as acupressure, moxibustion, exercises such as *tai chi* or *qi gong*, as well as Chinese herbal preparations and dietary therapy. ¹

Acupuncture is the stimulation of specific points on the body, by insertion of very fine, sterile, stainless steel needles to elicit a predictable physiological response. This stimulus may also be administered to the points using mild electrical stimulation (with or without needles), pressure techniques with the hands (acupressure) or the application of heat by various methods.

Acupuncturists assess a patient's syndrome or pattern of disharmony by using a set of diagnostic skills that involve four areas; questioning, palpation, visual inspection, and olfactory-auditory data collection. An acupuncturist determines the necessary treatment principle and strategy to prompt the patient back to functional harmony by discriminating the exact pattern of the body's physiological response to pathogenic factors.

The acupuncturist's skill at determining the appropriate points to treat is based upon his/her ability to accurately distinguish the presenting pattern, knowledge of correct points to address that pattern and knowledge of the proper type of stimulus for each point. The possession of this knowledge and skills is the key distinction between a professional certified acupuncturist and other health care providers who employ acupuncture only as a modality (stimulating points for their general effect without adjusting their choice of points to the specific patient's need).



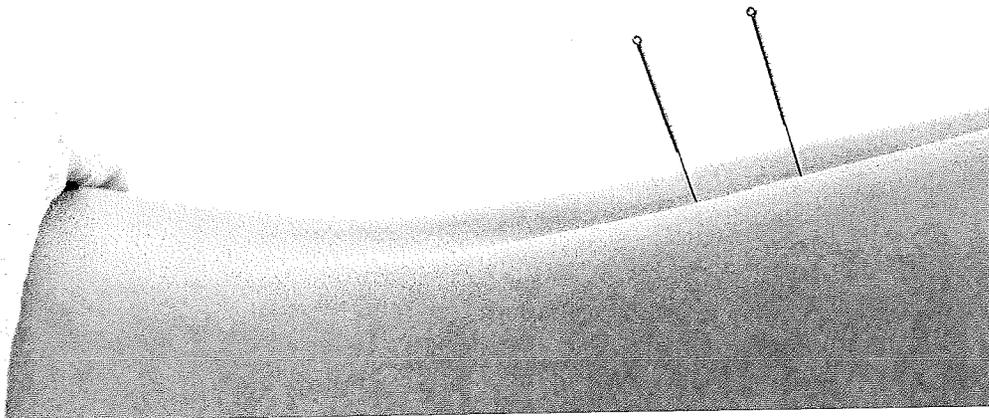
Use of Acupuncture

The Institute of Medicine recently identified 79 systematic reviews of acupuncture; placing acupuncture third in usage among all complementary and alternative (CAM) therapies.²

Acupuncture has been shown to provide generalized oxygenation and increased blood flow to specific areas of treatment. It also aids production of cortisone and other anti-inflammatory secretions and can increase the internal production of endorphins, the body's natural painkillers. In addition, a 2010 study from the University of Rochester in New York found that acupuncture can help relieve pain by triggering a natural pain-killing chemical called adenosine.³

A recent study of acupuncture — the most rigorous and detailed analysis of the treatment to date — found that it can ease migraines and arthritis and other forms of chronic pain. The researchers, who published their results in *Archives of Internal Medicine*, found that acupuncture outperformed sham treatments and standard care when used by people suffering from osteoarthritis, migraines and chronic back, neck and shoulder pain.⁴

A 2006 patient survey from the Alternative Medicine Integration Group based in Florida, found that 94% of study patients being treated by CAM therapies (including acupuncture) agreed that the program treatment helped reduce levels of pain.⁵



Acupuncture Can Relieve the Following Complaints

The World Health Organization recognizes acupuncture and Oriental medicine as effective for over 43 common ailments including: ⁶

Respiratory Disorders

Sinusitis, Rhinitis

Common cold

Tonsillitis

Sore throat

Hay fever

Bronchitis

Bronchial asthma

Disorders of the Eyes

Acute conjunctivitis

Myopia in children

Cataracts without complications

Central retinitis

Mental-Emotional Disorders

Anxiety

Depression

Stress

Insomnia

Addictions

Weight control

Musculo-skeletal Disorders

Frozen shoulder, Tennis elbow

Low back pain

Osteoarthritis and joint pains

Stiff neck

Tendinitis

Bursitis

Sprains

Injuries from auto accidents

Chronic fatigue syndrome

Fibromyalgia

Gastro-intestinal Disorders

Acute and chronic gastritis

Hyperacidity

Hiccoughs

Acute uncomplicated duodenal ulcer

Chronic duodenal ulcer (pain relief)

Acute and chronic colitis

Acute bacillary dysentery

Constipation

Diarrhea

Paralytic ileus



Neurological Disorders

Headache and Migraine

Dizziness

Trigeminal neuralgia

Facial palsy (within 3-6 months)

Pareses following stroke

Peripheral neuropathies

Meniere's disease

Neurogenic bladder dysfunction

Nocturnal enuresis

Intercostal neuralgia

Sciatica

Disorders of the Mouth

Toothache

Post extraction pain

Gingivitis

Acute and chronic pharyngitis

Ear Disorders

Ringing in ears

Deafness

Meniere's disease

Earache

Reproductive System Disorders

Infertility

Premenstrual syndrome (PMS)

Irregular menses

Menstrual cramps

Pelvic inflammatory disease (PID)

Menopausal symptoms

Morning sickness

Urinary incontinence

Impotence

Is use of acupuncture growing?

The American Hospital Association's Health Forum 2007 Complimentary and Alternative Medicine Survey of Hospitals found that 35% of the hospitals offering complementary medicine provide acupuncture as an outpatient service to the patients. Additionally, acupuncture is represented as one of the top six modalities in both outpatient and inpatient settings amongst those hospitals. ⁷

In the United States and abroad, the use of acupuncture and Oriental medicine is gaining widespread acceptance. In the United States there is an estimated 33,000 certified or licensed acupuncturists.

In the past two decades, acupuncture has grown in popularity in the United States. The 2007 National Health Interview Survey conducted by the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health (NIH) stated that acupuncture is being widely practiced by thousands of practitioners for relief or prevention of pain and for various other health conditions.

According to the 2007 National Health Interview Survey, the largest and most comprehensive survey of CAM use by American adults to date, acupuncture use has increased between 2002 and 2007 among adults. In 2007, almost 4 out of 10 adults had used CAM therapy in the past 12 months. Acupuncture is one of the CAM therapies that has seen an increase in usage during this time period. ²

Identifying a Qualified Acupuncturist

How do I find a qualified acupuncturist?

Look for a Diplomate of Acupuncture (NCCAOM)[®] or Diplomate of Oriental Medicine through the NCCAOM[®] *Find a Practitioner* search engine at www.nccaom.org.

The additional designation of licensed acupuncturist (L.Ac.) is awarded by a state regulatory board. Currently, 43 states plus the the District of Columbia, require NCCAOM certification or the passing of the NCCAOM examination(s) as one requirement for a state license to practice Acupuncture and/or Oriental medicine; however, one should always confirm the practitioner has a current state license to practice with the appropriate state board.

What training does an NCCAOM Diplomate of Acupuncture have?

Comprehensive training in traditional differential diagnosis and proper treatment methods requires that a Diplomate of Acupuncture (NCCAOM)[®] completes three to four academic years of education at the master's degree level in an acupuncture program accredited by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) or has completed an international education program which is substantially equivalent to ACAOM standards. ACAOM is the only accrediting body recognized by the United States Department of Education as the authority for quality education and training in acupuncture and Oriental medicine. In addition to graduation from an ACAOM accredited program, a Diplomate of Acupuncture (NCCAOM)[®] must demonstrate professional competency by passing NCCAOM certification examinations in Foundations of Oriental Medicine, Acupuncture, and Biomedicine as well as meet other NCCAOM certification requirements. The NCCAOM Diplomate training and competency verification is in sharp contrast to the acupuncture training of other healthcare professionals such as chiropractors or registered nurses or even medical doctors who typically receive 100-300 hours of abbreviated training. These other healthcare professionals provide acupuncture by treating a more limited number of points.⁸ Certified (and licensed) acupuncturists are also trained in standard medical history gathering, safety, ethics, common pharmaceuticals and supplements, and recognition of when to refer patients to other health care professionals or consult with other medical practitioners.

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7. Health Forum 2007 Complementary and Alternative Medicine Survey of Hospitals Summary of Results: August 2008; Chicago, Illinois.
8. Know Your Acupuncturist, Council of Colleges of Acupuncture and Oriental Medicine; <http://www.ccaom.org>; accessed January 29, 2014.

NCCAOM and its Diplomates

The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM®) is widely accepted as the most influential leader in the field of acupuncture and Oriental medicine. There are currently over 17,000 active NCCAOM Diplomates (NCCAOM certificate holders) practicing under an NCCAOM certification.

The NCCAOM, established in 1982, is a non-profit organization whose mission is to establish, assess, and promote recognized standards of competence and safety in acupuncture and Oriental medicine for the protection and benefit of the public. NCCAOM Acupuncture, Oriental Medicine and Chinese Herbology certification programs are accredited by the National Commission for Certifying Agencies (NCCA). NCCA's standards exceed the requirements set forth by the American Psychological Association and the United States Employment Opportunity Commission. As a requirement of accreditation the NCCAOM must submit annual reports to NCCA and must undergo a full reaccreditation every five years for each of its NCCA accredited programs. Additional information is available at <http://www.credentialingexcellence.org>.

Below are the service marks for the NCCAOM Certification Programs. The highlighted service mark is for the Acupuncture Certification Program.



The NCCAOM Diplomat of Acupuncture, Chinese Herbology, and Oriental Medicine programs carry the NCCA accreditation seal.



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Council of Colleges of
Acupuncture and Oriental Medicine

Council of Colleges of Acupuncture and Oriental Medicine*

Position Paper on Dry Needling

It is the position of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) that dry needling is an acupuncture technique.

Rationale

A recent trend in the expansion in the scopes of practice of western trained health professionals to include "dry needling" has resulted in redefining acupuncture and re-framing acupuncture techniques in western biomedical language. Advancement and integration of medical technique across professions is a recognized progression. However, the aspirations of one profession should not be used to redefine another established profession.

In addition proponents of "dry needling" by non-acupuncture professionals are attempting to expand trigger point dry needling to any systemic treatment using acupuncture needles and whole body treatment that includes dry needling by using western anatomical nomenclature to describe these techniques. It is the position of the CCAOM that these treatment techniques are the *de facto* practice of acupuncture, not just the adoption of a technique of treatment.

Terminology

The invasive procedure of dry needling has been used synonymously with the following terms:

- Trigger Point Dry Needling**
- Manual Trigger Point Therapy, when using dry needling**
- Intramuscular Dry Needling**
- Intramuscular Manual Therapy, when using dry needling**
- Intramuscular Stimulation, when using dry needling**

History

The system of medicine derived from China has a centuries-long continuous distinct practice with an extensive literature over 2000 years old. After President Nixon's visit to China in the early 1970s, public interest in and demand for

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acupuncture resulted in the establishment of first-professional degrees in acupuncture in the United States. Today over 50 accredited¹ first-professional colleges teach a diversity of styles of health care utilizing acupuncture, Chinese herbology, manual techniques such as tuina (Chinese therapeutic massage), nutrition, and exercise/breathing therapy. Individuals who attain this degree undergo a rigorous training program at a minimum standard of three academic years that contains 450 hours in biomedical science (biology, anatomy, physiology, western pathology, and pharmacology), 90 hours in patient counseling and practice management, and 1365 hours in acupuncture. Of the 1365 hours in acupuncture, 660 hours must be clinical hours.

Acupuncture is a system of medicine that utilizes needles to achieve therapeutic effect. The language used to describe and understand this effect is not limited and is articulated in both traditional and modern scientific terms. The National Institutes of Health has recognized the efficacy of acupuncture in its consensus statement of 1997² and continued funding of research. It is clear that other professions such as physical therapy and others also recognize the efficacy of acupuncture and its various representations such as dry needling due to the fact that they are attempting to use acupuncture and rename it as a physical therapy technique.

Dry needling is an acupuncture technique

As a system of treatment for pain, acupuncture relies on a category of points derived from the Chinese language as "ashi" (阿是) points. "Ashi" point theory describes the same physiological phenomenon identified as "trigger points," a phrase coined by Dr Janet Travell³ and dates to the Tang Dynasty (618-907). While Dr. Travell coined the phrase "trigger point", the physiological phenomenon has been long known to acupuncturists. Dr. Travell herself had contact with acupuncturists and chiropractors interested in acupuncture in the Los Angeles area in the 1980s. Dr. Mark Seem, author of *A New American Acupuncture*⁴, discussed the similarity of their techniques in the 1990s.⁵

Modern contributors from the field of acupuncture in the specialization of dry needling techniques are:

Dr. Mark Seem, Ph. D., L. Ac., published the textbook *A New American Acupuncture* covering the topic of dry needling in 1993. His books have been published for over two decades.

Matt Callison, L. Ac., is the founder of the Sports Medicine Acupuncture® certification program and the author of *Motor Points Index*. The continuing education certification program is available to licensed acupuncturists through a private seminar company and through postgraduate studies at the New England School of Acupuncture.

Whitfield Reaves, L. Ac. is the author of *The Acupuncture Handbook of Sports Injuries and Pain: A Four Step Approach to Treatment*. He also offers a

postgraduate continuing education program in Sports Acupuncture only for licensed acupuncturists.

From the above sources it is apparent that acupuncture has an established history of using treatment utilizing what are now labeled trigger points.

Documented practice of "dry needling" by acupuncturists

The National Commission for the Certification of Acupuncture and Oriental Medicine (NCCAOM), the certifying board for acupuncture, completed a job task analysis in 2003 and again in 2008. The analysis documented the prevalence of actual use of dry needling techniques, i.e. the treatment of trigger points or motor points with acupuncture needles, by practicing acupuncturists. In 2003, 82% of acupuncturists surveyed used needling of trigger points in patients that presented with pain. Of the patients that present for acupuncture treatment, it is estimated that 56% present with trigger point pain. The others present for non-pain conditions such as non-trigger point pain, digestive disorders, infertility and many other conditions. The other 18% of acupuncturists used acupuncture needling techniques in non-trigger point locations. These findings document that acupuncturists are well trained to use and have consistent historical usage of trigger and motor point "dry needling" treatment. Dry needling represents a substantial daily practice among American acupuncturists.

History of "dry needling" in North America

Dr. Chan Gunn, M.D., is the founder of dry needling in Canada. He wrote in 1976, "As a first step toward acceptance of acupuncture by the medical profession, it is suggested that a new system of acupuncture locus nomenclature be introduced, relating them to known neural structures."⁶ One may reasonably infer from this statement that Dr. Gunn believed that in order for acupuncture to be accepted in Western medicine, the technique would need to be redefined. Using a different name for the same technique does not rise to the level of creating a new technique. Dr. Chan Gunn's dry needling seminars are only four days in length.

Jan Dommerholt has published extensively on the technique and teaches dry needling to both western trained health professionals and licensed acupuncturists, but his teaching has been focused on the profession of Physical Therapy (PT). He argues that dry needling is a new emerging western technique described in western scientific terms. He is also attempting to redefine acupuncture based solely on eastern esoteric concepts.

A current author and provider of dry needling courses, Yun-tao Ma, Ph.D., extends dry needling beyond trigger points to include acupuncture points. He describes the points according to the neuroanatomical location and effects and calls them "Acu reflex" points. It is this adaptation and renaming of acupuncture to provide total body treatment that poses the greatest risk to the public, as it circumvents established standards for identical practice, i.e., acupuncture, without the rigorous training of acupuncture and the licensing of such.

It is the position of the CCAOM that any intervention utilizing dry needling is the practice of acupuncture, regardless of the language utilized in describing the technique.

State Board of Medicine complaints against acupuncturists for dry needling

In 2009, a physical therapist submitted a complaint to the Maryland Board of Acupuncture concerning the use of the term dry needling in chart notes by an acupuncturist. The Maryland Board of Acupuncture correctly dismissed the complaint because the procedure was done by a licensed acupuncturist trained in the use of dry needling, *i.e.*, acupuncture.

In filing the complaint, the physical therapist was not asserting that the acupuncturist caused any harm or potential of harm to the patient. Rather, the physical therapist asserted that the acupuncturist used proprietary language that was unique to physical therapy, when in fact the acupuncturist was using language that was common across professions. The Little Hoover Commission, in its 2004 report to the California legislature concluded, "interactions with other health care providers, including collaboration and referrals, as well as with many members of the public, benefit from the use of common, Western-based diagnostic terminology"⁷

Summary Position of the CCAOM on Dry Needling

It is the position of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) that dry needling is an acupuncture technique.

It is the position of the CCAOM that any intervention utilizing dry needling is the practice of acupuncture, regardless of the language utilized in describing the technique.

Adopted November 2010
Updated May 2011

¹ The Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) is recognized by the U.S. Department of Education to accredit colleges of acupuncture and Oriental medicine and authorizes such colleges to confer Master's level first-professional degrees.

² <http://consensus.nih.gov/1997/1997Acupuncture107html.htm>.

³ Travel, Janet G., and David G. Simons. Myofascial pain dysfunction: the trigger point manual. Lippincott Williams & Wilkins, 1983, Print.

⁴ Seem, Mark. *A new American acupuncture: acupuncture osteopathy, the myofascial release of the bodymind*. Blue Poppy Press, 1993. Print.

⁵ Private communication of October, 2007 with Whitfield Reaves, L. Ac., who attended study groups with Dr. Travell in the 1980s, and in a letter from Dr. Mark Seem to Jan Dommerholt November 11, 2007. Seem relates his invitation and demonstration of acupuncture "dry needling" techniques to Dr. Travell in New York City in the 1990s.

⁶ Gunn, CC, Ditchburn FG, King MH, Renwick GJ, *Acupuncture loci: a proposal for their classification according to their relationship to known neural structures*, *Am J Chin Med*, 1976 Summer; 4(2): 183-95.

⁷ Milton Marks "Little Hoover" commission on California State Government Organization and Economy by the UCSF Center for the Health Professions, *Acupuncture in California: Study of Scope of Practice*, May 2004, pg. 13.



American Association of Acupuncture and Oriental Medicine (AAAOM) Position Statement on Trigger Point Dry Needling (TPDN) and Intramuscular Manual Therapy (IMT)

Summary

The American Association of Acupuncture and Oriental Medicine Blue Ribbon Panel on Inter-professional Standards has determined that dry needling and any of its alternate designations, including intramuscular manual therapy, trigger point needling, functional dry needling, intramuscular stimulation or any other method by which a needle is inserted to effect therapeutic change, is, by definition, the practice of acupuncture.

Rationale

1. Acupuncture, as a procedure, is the stimulation of anatomical locations on the body, alone and in combination, to treat disease, injury, pain, and dysfunction and to promote health and wellness.
2. Acupuncture, as a procedure, includes the invasive stimulation of said locations by the insertion of needles and the non-invasive stimulation of said locations by thermal, electrical, chemical, light, mechanical or other manual therapeutic methods.
3. Acupuncture, as a therapeutic intervention and medical practice, is the study of how the various acupuncture procedures are applied in health care.
4. Trigger point dry needling, dry needling, functional dry needling, and intramuscular manual therapy, or any other pseudonym describing acupuncture procedures, are, by definition, the practice of acupuncture.
5. In the interest of public safety, non-acupuncture boards should not regulate the practice of acupuncture.

Nationally Recognized Acupuncture Standards

The AAAOM endorses the educational standards set forth by the Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM). The ACAOM is the sole agency recognized by the United States Department of Education to set educational standards for the procedure and practice of acupuncture.

The AAAOM endorses the state licensure qualifying standards set forth by the National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM). The NCCAOM is the sole agency recognized by the Institute for Credentialing Excellence's (ICE) National Commission on Certifying Agencies (NCCA) to qualify acupuncturists for licensure.

State regulatory boards for licensed health care professions other than acupuncture have begun to recognize the procedure and practice of acupuncture by other names, such as “dry needling” and “trigger point dry needling.” At present, this is being done primarily by physical therapy boards in an attempt to expand the scope of practice for the physical therapy profession. Scope of practice expansion attempts made in this manner preclude necessary and adequate educational and safety standards for the procedure and practice of acupuncture. Forty-four (six pending) states plus the District of Columbia have statutorily defined acupuncture and the educational and certification standards required for acupuncture licensure. Current medical literature is consistent with the definitions of both the procedure and practice of acupuncture as provided by state practice acts.¹⁻²¹

Historical Precedents

Trigger point dry needling and intramuscular manual therapy are aliases used in the marketing of a subset of acupuncture techniques described in the field of acupuncture as “ashi point needling.”² A reasonable English translation of ashi points is “trigger points”, a term used by Dr. Janet Travell in her landmark 1983 book *Myofascial Pain Dysfunction: The Trigger Point Manual*.³ Dorsher et al.,⁴ determined that of the 255 trigger points listed by Travell and Simons, 234 (92%) had anatomic correspondence with classical, miscellaneous, or new acupuncture points listed in Deadman et al.,⁵ an internationally-recognized acupuncture reference book.

Modern authorities agree and describe dry needling as acupuncture.^{6,7,8} Mark Seem discussed dry needling in *A New American Acupuncture* in 1993.⁹ Matt Callison describes dry needling in his *Motor Points Index*¹⁰ as does Whitfield Reaves in *The Acupuncture Handbook of Sports Injuries and Pain: A Four Step Approach to Treatment*.¹¹ Yun-tao Ma, author of *Biomedical Acupuncture for Sports and Trauma Rehabilitation Dry Needling Techniques*, describes dry needling as acupuncture and provides a rich historical explanation of why.¹²

C. Chan Gunn, “Acupuncture loci: A proposal for their classification according to their relationship to known neural structures,” *American Journal of Chinese Medicine*, 1976¹³ and Peter Baldry, *Acupuncture, Trigger Points and Musculoskeletal Pain: A Scientific Approach to Acupuncture for Use by Doctors and Physiotherapists in the Diagnosis and Management of Myofascial Trigger Point Pain*, 2005,¹⁴ also acknowledge dry needling procedure and practice to be equivalent to acupuncture procedure and practice.

These examples demonstrate a Western medical movement to rename the procedure and practice of acupuncture as dry needling by providers other than acupuncturists. The examples listed above affirm that there is a literary tradition acknowledging the term “dry-needling” to be synonymous with acupuncture.

Concerns

The AAAOM has the following additional specific concerns:

- 1) No standards of education have been validly determined to assure that physical therapists (PT) using TPDN are able to provide the public with a safe and effective procedure.¹⁵
- 2) Redefining identical medical procedures and thereby circumventing or obscuring established laws regarding their safe practice is irresponsible
- 3) In many states, the addition of TPDN to physical therapy practice is being determined by physical therapy regulatory boards, deleteriously circumventing transparency and public health safety protections provided by standard legislative process

The U.S. Department of Education recognizes ACAOM as the sole accrediting agency for acupuncture training institutions as well as their Master's and Doctoral Degree programs.^{16, 17} Standards of training in acupuncture are well established, and designed to support safe and effective practice.^{18, 19} Attempts to circumvent acupuncture training standards, licensing or regulatory laws by administratively retitling acupuncture as "dry needling" or any other name is confusing to the public, misleads the public as to therapeutic intervention expected, and, through lack of meaningful education and practice regulation, creates a significant endangerment to public welfare.

This actual risk of endangerment to public welfare has been investigated by at least one malpractice insurance company that has stated it will cancel policies for physical therapists "engaging in a medical procedure for which they have no adequate education or training."²⁰ Recent actions by state medical regulatory authorities have identified and acted upon the aforementioned risk.²¹

In conclusion, the AAAOM strongly urges legislators, regulators, advisory boards, advocates of public safety, and medical professional associations to carefully consider the impact of trends in scope of practice expansion issues.

¹ <http://www.ncbi.nlm.nih.gov/pubmed/15108608>

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³ Travell J, Simons D. *Myofascial Pain Dysfunction: The Trigger Point Manual*. Philadelphia, PA: Lippincott Williams & Wilkins; 1983.

⁴ Dorsher PT. Trigger Points And Acupuncture Points: Anatomic And Clinical Correlations. *Medical Acupuncture*. 2006;17(3).

⁵ Deadman P, Al-Khafaji M, Baker K. A Manual of Acupuncture. Kingham, Oxfordshire Journal of Chinese Medicine Publications

⁶ When To Select Observational Studies as Evidence for Comparative Effectiveness Reviews Prepared for: The Agency for Healthcare Research and Quality (AHRQ) Training Modules for Systematic Reviews Methods Guide www.ahrq.gov Effective Health Care Program. "The AHRQ Training Modules for the Systematic Reviews Methods Guide:..." *The AHRQ Training Modules for the Systematic Reviews Methods Guide: An Introduction*. Ahrq.gov. Web. 06 Feb. 2012. <<http://www.slideshare.net/AHRQEHCPProgram/the-ahrq-training-modules-for-the-systematic-reviews-methods-guide-an-introduction>>.

⁷ Alberta Heritage Foundation for Medical Research Health Technology Assessment Unit. *Acupuncture: Evidence from systematic reviews and meta-analyses* 2002 Mar. Used in glossary of "Acupuncture for Osteoarthritis." *Centers for Medicare & Medicaid Services*. Web. 14 Jan. 2012. <<http://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?TAId=19>>.

⁸ *Acupuncture for Osteoarthritis*. Rockville, MD: U.S. Dept. of Health and Human Services, Public Health Service, Agency for Healthcare Research and Quality, 2003. Print. This definition is also used in the glossary of "Acupuncture for Osteoarthritis." Centers for Medicare & Medicaid Services. "Acupuncture for Osteoarthritis." Centers for Medicare & Medicaid Services. Web. 14 Jan. 2012. <<http://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?TAId=19>>1

⁹ Seem M. *A New American Acupuncture: Acupuncture Osteopathy, the Myofascial Release of the Bodymind*. Boulder, CO: Blue Poppy Press; 1993.

¹⁰ Callison M. *Motor Point Index: An Acupuncturist's Guide to Locating and Treating Motor Points* San Diego, CA: AcuSport Seminar Series LLC; 2007.

¹¹ Reaves W, Bong C. *The Acupuncture Handbook of Sports Injuries & Pain*. Boulder, CO: Hidden Needle Press; 2009.

¹² Ma, Yun-tao. *Biomedical Acupuncture for Sports and Trauma Rehabilitation Dry Needling Techniques*. New York: Elsevier; 2010.

¹³ Gunn, C. Chan. Acupuncture loci: A proposal for their classification according to their relationship to known neural structures. *American Journal of Chinese Medicine* 4.No. 2 (1976): 183+. Print

¹⁴ Baldry, Peter. *Acupuncture, Trigger Points and Musculoskeletal Pain: A Scientific Approach to Acupuncture for Use by Doctors and Physiotherapists in the Diagnosis and Management of Myofascial Trigger Point Pain*. 3rd ed. Edinburgh: Elsevier/Churchill Livingstone, 2005. Print. ISBN 0 443 06644 2. Preface.

¹⁵ Commission on Accreditation in Physical Therapy Education (CAPTE) – Accreditation Handbook – November 2011

¹⁶ <http://ope.ed.gov/accreditation/>

¹⁷ <http://www.acaom.org/about/>

¹⁸ <http://www.acaom.org/documents/accreditation-manual.pdf>

¹⁹ <http://www.nccaom.org/applicants/eligibility-requirements>

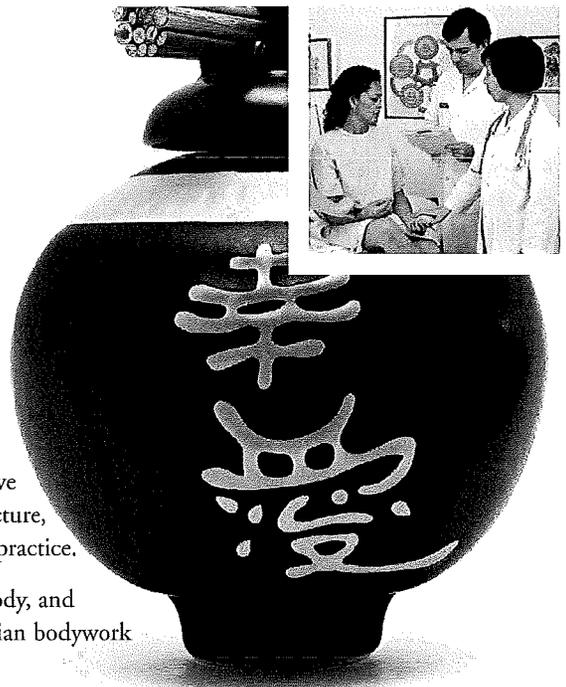
²⁰ Letter from Allied Professional Services [on file at AAAOM]

²¹ Letter from the Oregon Medical Board [<http://www.oaom.com/wp-content/uploads/2010/06/DryNeedling.pdf>]



Council of Colleges of
Acupuncture and Oriental Medicine

Committed to Excellence in Acupuncture and Oriental Medicine Education



Know Your Acupuncturist

Practitioners whose graduate education is in Acupuncture & Oriental Medicine (AOM) receive approximately 80% of their education exclusively in this field and undergo extensive clinical training averaging 3-4 years. Other healthcare practitioners may only use acupuncture, which is one of the many therapies of Oriental Medicine, as a technique in their primary practice.

A philosophical distinction of Oriental Medicine is its whole person approach of mind, body, and spirit in a comprehensive energetic healthcare system that includes acupuncture, herbs, Asian bodywork (e.g. acupressure, tui na, shiatsu), nutrition, tai chi, qi gong, and meditation.

This chart is designed to illustrate the varying levels of education undertaken by healthcare professionals in acupuncture only and not in related curriculum, such as in the biosciences. Acupuncture should only be administered by a practitioner who has specific education in this field due to risk of improper needling, inadequate understanding of Oriental medical diagnostic procedures, transmission of disease, imbalancing of energy, or ethical violations. Ask your practitioner about his or her education in order to ensure that you receive the most professional acupuncture care available for your optimal health and wellness.

www.ccaom.org

<i>Contact Hours in Acupuncture Education</i>	<i>Practitioner Title</i>	<i>Application</i>
3-4 years (1500 - 2000 hours in acupuncture)*	Typically a Licensed Acupuncturist (LAc)** who has obtained a degree/diploma from an ACAOM-accredited college and has passed the national certification exams administered by the NCCAOM.***	A broad range of health issues, including chronic disease, pain, internal medicine, rehabilitation, and prevention
300 hours or less in acupuncture	Typically a medical doctor, osteopath, naturopath, or chiropractor who uses acupuncture as an adjunctive technique. The World Health Organization (WHO) recommends that medical doctors who wish to use acupuncture as a technique in their clinical work have a minimum of 200 hours of training, with the amount of training for other health personnel being variable according to the specific application. For a full course of training, WHO recommends 1,500 hours of training in acupuncture for physicians.	Pain, basic ailments
100 hours or less in acupuncture	Typically a detox/auricular acupuncture technician or chiropractor (detox techs are generally limited to 5 points on the ear)	Addiction & pain
Continuing education seminars provide approximately 40-50 contact hours in "dry needling."	Typically a physical therapist who uses an acupuncture needle to perform dry needling in the treatment of muscle trigger points	Muscular-skeletal pain

*ACAOM's total curriculum requirement for an acupuncture-only training program is 1905 hours and ranges between 1950-2600 hours for ACAOM-accredited and candidate acupuncture only training programs, with a minimum of 450 hours in the biomedical clinical sciences.

**Some states also designate the licensing title (non-degree) as DOM or DAC, or Acupuncture Physician. Licensed Acupuncturists may have also obtained an OMD, PhD, or DAC for non-extensive post-graduate training. Thus, it is important to ask where such a title was received.

***ACAOM (Accreditation Commission for Acupuncture & Oriental Medicine, www.acaom.org); NCCAOM (National Commission for the Certification of Acupuncture & Oriental Medicine, www.nccaom.org)

Narrative Review

Iatrogenic pneumothorax: safety concerns when using acupuncture or dry needling in the thoracic region

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Background: Pneumothorax is a very rare but serious complication associated with acupuncture and dry needling around the thoracic region. Physiotherapists and other health practitioners should be aware of the risks associated with needling in this region and should take care to minimize the possibility of an iatrogenic pneumothorax.

Findings: An awareness of the signs and symptoms of a pneumothorax is necessary for practitioners using acupuncture and dry needling in the thoracic region. Understanding the normal anatomy and its variants can minimize risk associated with needling practices in this region. Various technique modifications are suggested so that the pleura or lungs are avoided while using acupuncture or dry needling in the thoracic region.

Discussion/Conclusion: Acupuncture and dry needling in this region administered by well-trained physiotherapists and other health practitioners is very safe; however, to maximize safety therapists should consider the relevant anatomy and not practise using advanced acupuncture and dry needling techniques without adequate competency-based training.

Keywords: Acupuncture, Education, Iatrogenic disease, Medical error, Pneumothorax

Background

Pneumothorax is defined as air in the pleural space. For air to enter the pleural cavity one of the following events must have occurred:¹ direct communication between the alveolar spaces and the pleura; direct or indirect communication between the atmosphere and the pleural space; or gas producing organisms are evident in the pleural space. A tension pneumothorax develops when air is trapped under a positive pressure in the pleural cavity.²

The use of acupuncture and dry needling by physiotherapists and other health practitioners is increasing internationally. Systematic reviews and clinical guidelines have highlighted the benefits of acupuncture and dry needling as part of an overall management plan for patients with various musculoskeletal disorders including low back pain, pelvic girdle pain, cervical spine pain, whiplash-associated disorder, tension type headaches, and migraines.³⁻¹⁰ Pneumothorax is a very rare but serious complication associated with acupuncture and dry needling around the thoracic region.¹¹ In particular needling to upper trapezius (GB21) and to the

thoracic erector spinae and rhomboid musculature (bladder channels) have been shown to be commonly associated with iatrogenic pneumothorax. Other regions around the thorax which pose a risk of pneumothorax include the sub-clavicular region, the supra-clavicular region, intercostal spaces, interspinal spaces, and congenital foramen associated with the sternum, the suprascapular, and infrascapular fossa. Physiotherapists and other medical practitioners should be aware of the risks associated with needling around the thorax and should take care to minimize the likelihood of inadvertently creating a pneumothorax.

Classification and aetiology of pneumothorax

Pneumothoraces are classified as spontaneous or traumatic. Spontaneous pneumothorax is labelled as primary where there is no underlying lung disease present, or secondary which is associated with pre-existing lung disease. In primary spontaneous pneumothorax, 91% of cases are smokers, with the relative risk increasing with the number of cigarettes smoked, particularly in males.^{12,13} Other risk factors for primary spontaneous pneumothorax include a tall slim body type, Marfan's syndrome, pregnancy, or a family history.^{12,14} Secondary spontaneous pneumothorax may be associated with chronic obstructive

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pulmonary disease (COPD), tuberculosis, sarcoidosis, cystic fibrosis, severe asthma, idiopathic pulmonary fibrosis, malignancy, necrotising pneumonia and HIV associated *Pneumocystis carinii* pneumonia.^{1,15} Secondary spontaneous pneumothorax has also been associated with connective tissue disorders including rheumatoid arthritis (RA), ankylosing spondylitis (AS), scleroderma, systemic lupus erythematosus (SLE), polymyositis, catamenial pneumothorax and Ehlers-Danlos syndrome.¹⁻² The use of oral corticosteroids has also been associated with spontaneous pneumothorax.¹⁶

The incidence of primary spontaneous pneumothorax is 7.4–24/100 000 in men and 1.2–10/100 000 in women.^{1,13,17} Primary spontaneous pneumothorax occurs predominantly in adults in their second and third decades of life.¹² The incidence of secondary pneumothorax is 6.3/100 000 in males and 2.0/100 000 in females;¹⁷ however, in individuals with COPD the incidence increases to 26/100 000 with a 3.5-fold increase in mortality associated with secondary spontaneous pneumothorax.¹² Secondary spontaneous pneumothorax has been shown to peak in incidence in the 60- to 65-year age bracket.¹²

Traumatic pneumothorax may be iatrogenic or non-iatrogenic. Causes of non-iatrogenic pneumothorax include penetrating or non-penetrating traumatic injuries, rib fractures, and high risk professions or sports including diving or flying. The common causes of iatrogenic pneumothorax include transthoracic needle biopsy, central venous subclavian vein catheterization, thoracentesis, transbronchial lung biopsy, pleural biopsy, intercostal nerve block, suprascapular nerve block, tracheostomy, nasogastric feeding tube placement, nephrectomy, gastrostomy, cardiopulmonary resuscitation, and positive pressure ventilation.^{1,18–20} Iatrogenic pneumothorax has also been reported to occur with medical research utilizing electromyography fine wiring to assess activation of muscles including levator scapulae, trapezius, serratus anterior, rhomboids, the diaphragm, cervical and thoracic paraspinal muscles, intercostals, pectoralis major and minor, supraspinatus, infraspinatus, and subscapularis.^{21–23} Similarly injections of prolotherapy solutions, botulinum toxin, anaesthetic, or cortisone into ligaments and muscles in the thoracic region have been associated with iatrogenic pneumothoraces.^{21,24,25}

Acupuncture- and Dry Needling-induced Iatrogenic Pneumothorax

Incidence

Acupuncture and dry needling has been identified as an additional cause of iatrogenic pneumothorax.²⁶ The incidence of acupuncture-induced pneumothorax is less than 1/10 000,^{27,28} which is classed as very rare by the WHO classification.²⁹ There have however been in excess of 100 case reports of iatrogenic

pneumothorax due to acupuncture and dry needling reported in the research literature, including four cases of death.^{25,27,28,30–34} Most iatrogenic pneumothoraces associated with acupuncture and dry needling are unilateral, although case studies of bilateral iatrogenic pneumothoraces have been reported.^{16,35}

Large prospective investigations into the incidence of acupuncture-induced iatrogenic pneumothorax have been conducted in the United Kingdom, Japan, Czechoslovakia, Switzerland, and Germany. During the survey of adverse events following acupuncture studies in the United Kingdom over 66 000 consultations were performed by medical practitioners and physiotherapists and there were no pneumothoraces.^{36–39} Similarly in Japan, no pneumothoraces occurred during a 6-year survey of 65 482 consultations conducted by acupuncture therapists.^{40,41} In Czechoslovakia, the incidence of acupuncture-induced iatrogenic pneumothorax was 2 in 139 988 equating to 1 in 69 994 consultations by hospital-based medical physicians.⁴² German acupuncture trials (GERAC) have been the largest prospective studies into the efficacy, effectiveness, and safety of acupuncture by well-trained medical practitioners to date. From the initial 763 900 consultations reviewed during GERAC, Melchart *et al.*⁴³ reported an incidence of 1/381 950 consultations; however, after 2 338 146 consultations, Witt *et al.*⁴⁴ reported the incidence of iatrogenic pneumothorax to be 1/1 170 000. The programme for evaluation of patient care with acupuncture (PEP-Ac) provided further analysis of the GERAC trials, summing that in over 4 000 000 acupuncture consultations by medical practitioners three pneumothoraces occurred equating to a risk of 1/1 300 000 consultations.^{45,46} However not all of the consultations included in the above cited prospective studies involved needling in the thoracic region. It is important to establish if a pneumothorax is spontaneous or iatrogenic because with primary spontaneous pneumothorax, the risk of recurrent pneumothorax is increased while with iatrogenic pneumothorax this risk is not increased.¹⁷

Clinical features

A good working knowledge of the clinical features of pneumothorax is vital to physiotherapists and other health practitioners practising acupuncture or dry needling in and around the thoracic region. This facilitates its early recognition and may improve the information and consent processes for these procedures. It also aids the diagnosis of spontaneous pneumothorax masquerading as a thoracic musculoskeletal condition in patients with thoracic region pain presenting for acupuncture or manual therapy.

Such presentations are well described in the physical therapy literature.^{31,47,48}

The signs and symptoms of a pneumothorax may include dyspnoea (shortness of breath) on exertion, tachypnoea (increased respiratory rate), chest pain, dry cough, cyanosis, diaphoresis (sudomotor activity), and decreased breath sounds on auscultation over the affected region.^{49,50} In rare circumstances a tension pneumothorax, which is life threatening due to displacement of mediastinal structures and resultant compromised cardiopulmonary function, may develop.⁵⁰

The symptoms of acupuncture-induced iatrogenic pneumothorax commonly do not occur until after the treatment session, sometimes taking several hours to develop. Patients need to be cautioned as to the possible symptoms of pneumothorax and what to do in the event of such symptoms. Therapists should consider if the patient has a pre-existing lung condition or any other risk factors predisposing them to spontaneous pneumothorax and thereby iatrogenic pneumothorax. Another consideration may be if the patient is going to be exposed to barometric stress, such as flying or scuba diving.

In the event of a suspected pneumothorax, either on presentation or following acupuncture or dry needling, chest percussion and auscultation may reveal hyper-resonance and decreased air entry. A plain chest X-ray should be performed if such signs are found, or indeed if any uncertainty about the diagnosis of pneumothorax remains as the diagnostic validity of percussion and auscultation in detecting pneumothorax is limited.⁵⁰ Prompt referral for medical management is indicated should a pneumothorax be found. Degrees of lung collapse have been graded as mild (<20%), moderate (20–40%), and severe (>40%).⁵¹ In otherwise healthy patients with mild iatrogenic pneumothorax monitoring as either an inpatient or an outpatient, is usually sufficient to ensure that the lung re-inflates without incident.¹⁷ Oxygen saturation levels should be considered and oxygen administered as necessary.⁴⁹ Should a larger moderate to severe pneumothorax or a tension pneumothorax develop a chest drain (pigtail catheter or tube thoracostomy) will usually be utilized over a period of days as re-expansion of the lung is achieved.

Anatomical considerations

Consideration of the relevant anatomy by adequately trained practitioners will further reduce the risk of an iatrogenic pneumothorax. The primary areas associated with acupuncture- or dry needling-induced pneumothorax are the regions of thorax including the upper trapezius, paraspinal, medial scapular, and subclavicular regions.^{16,17,26,27,31,35,48,52–56} Anatomically the lung

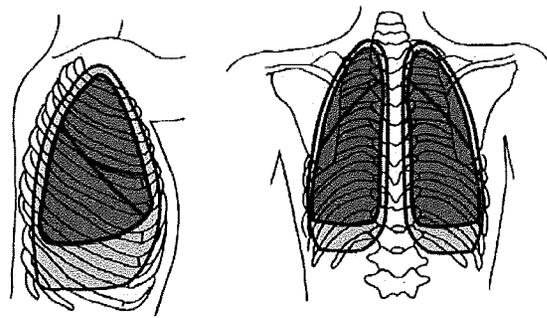


Figure 1 Right lateral view and posterior view of lungs and pleural lining relative to skeletal structures in the thoracic region.

fields extend to the sixth rib anteriorly at the mid-clavicular line, to the eighth rib laterally at the mid-axillary line and to the tenth rib posteriorly. The pleura extends a further two ribs below each of these levels (Fig. 1). This is particularly important to note posteriorly where at the lateral border of the erector spinae the pleura extends down to the twelfth rib and care should be taken when needling iliocostalis or the outer bladder channel.

The apex of the lung extends 2–3 cm above the clavicular line and care should be taken when needling upper trapezius or GB21. In individuals who smoke, additional care should be taken when needling cephalad to the first rib or in the supraclavicular region to avoid puncturing a bulla (a sharply bordered region in emphysematous lung with a diameter of less than 1 cm and a thickness of less than 1 mm) or a bleb (an air-filled cavity of the pulmonary pleura) formation which occur predominantly in the apex of the lung.^{1,48}

There are three areas in the thorax with congenital anomalies of relevance to acupuncture and dry needling regions. Congenital foraminae in the infraspinous fossa of the scapula with diameters up to 2–5 mm have been described in 0.8–5.4% of individuals.^{57,58} Such foramina have also been described in the supraspinous fossa. In 5–8% of individuals a congenital foramina exists due to incomplete ossification and fusion of the sternal plates which most commonly occur at the level of the fourth intercostals plate.^{59–61} A congenital sternal foramen is usually not able to be palpated due to overlying muscle tendon fibres and connective tissue.⁵⁹ It is, however, more likely that cardiac tamponade due to injury of the heart or pericardium could occur if needling was performed deeper than 13–25 mm directly over the sternum.⁶² Consequently physiotherapists are advised to needle superficially in an oblique cephalad direction when performing acupuncture or dry needling over the sternum.

Vulnerable areas in the thoracic region

Based on post-mortem examinations, Peucker *et al.* concluded that needle puncture depths of 10–20 mm



Figure 2 Needling directly over the fourth rib using an acute angle of penetration and straddling the rib with two fingers.

parasternally or in the region of the mid-clavicular line could result in a pneumothorax.^{28,48,59} Posteriorly, the surface of the lungs is 15–20 mm beneath the dermal surface in the parascapular zone.^{28,59} Case studies have been reported describing iatrogenic pneumothoraces from needling of ST11 and ST12 in the supraclavicular region and LU2, ST2, and KI27 in the infraclavicular region; KI22 and KI27 parasternally, ST12 to ST18 in the mid-clavicular line, and BL41 to BL50, rhomboids, serratus posterior superior, levator scapulae, splenius cervicis, longissimus thoracis, iliocostalis thoracis, semispinalis thoracis, cervicis and capitis in the medial scapular region.^{16,17,27,28,35,52,54,55}

When needling around the thoracic region the risks and benefits of maintaining site specificity should be considered. Numerous clinical trials and recent brain imaging studies have revealed that there is no significant difference between needling directly onto an acupuncture point compared with sham needling at a point which is a marginal distance from an actual acupuncture point.^{63,64} Hence needling points which lie directly over intercostal spaces should be avoided^{56,65} as potential benefits do not outweigh the risks. It is safer to straddle a rib with two fingers and needle directly over the rib at an acutely oblique angle (Fig. 2). Alternative safer techniques include more superficial forms of dermal needling, such as Baldry dry needling or Japanese acupuncture, using acupuncture needles of a shorter length.

Reducing the risk of iatrogenic pneumothorax

While iatrogenic pneumothorax is a very rare adverse event in association with acupuncture and dry needling³⁸ and virtually all pneumothoraces fully resolve and mortality is extremely remote, due care to prevent a pneumothorax occurring should always be observed. Additional care should be taken when dry needling or acupuncture shoulder muscles that

have been associated with fine wire electromyography-induced iatrogenic pneumothoraces or acupuncture-induced pneumothoraces such as subscapularis, supraspinatus, infraspinatus, levator scapulae, pectoralis major and minor.^{21–23,25,65} Due to the possibility of a congenital foramen in the supraspinous or infraspinous fossa acupuncture and dry needling in this region should be directed at an oblique angle along the fossa towards the glenohumeral joint. When dry needling pectoralis major needling may be performed via a pincer grip hold in the anterior axillary region, gripping the pectoralis major between thumb and fingers, and needling performed across the fibres of the muscle. Dry needling of pectoralis minor may be performed by needling obliquely towards the coracoid process. Dry needling of the origin of levator scapulae may be performed safely if the patient's scapula is able to wing off the chest wall by lying the patient on the ipsilateral side and elevating the arm or alternatively if the patient lies on their contralateral side with their ipsilateral arm held behind their back (Fig. 3). Due to the risk of pneumothorax, it is advisable not to attempt to needle the origin of levator scapulae if the medial border of the scapulae is not able to wing off the chest wall.

Dry needling muscles on the lateral chest wall including serratus anterior and latissimus dorsi or acupuncture points in the mid-axillary line including SP17 to SP21, GB21, and GB22 also need to be considered to increase safety. Once again the technique of straddling a rib with two fingers and needling directly over the rib at an acutely oblique angle should be utilized. Latissimus dorsi can be dry needled safely by using a pincer grip hold and needling across the fibres as the muscle is lifted off the chest wall.

Needling of GB21 and particularly upper trapezius trigger points has been associated with iatrogenic pneumothorax.^{26,35,53,55} When needling upper trapezius or GB21 with the patient in a prone position, the bulk of upper trapezius is lifted in a cephalad direction using a broad pincer grip. While holding the muscle bulk the physiotherapist should attempt to lay the thumb of their non-needling hand that is holding the muscle bulk along the line of the first rib. Maintaining the position of the thumb, the upper trapezius is needled in a cephalad direction cephalad of the thumb. If a pecking style of dry needling is being utilized, the physiotherapist should ensure that the needle does not move in a caudad direction. If the acupuncture needle is being left *in situ*, its cephalad direction should be monitored to decrease the risk of upper trapezius grabbing the needle and drawing it towards the apex of the lung. Arm position should also be considered. The patient's arms may be down

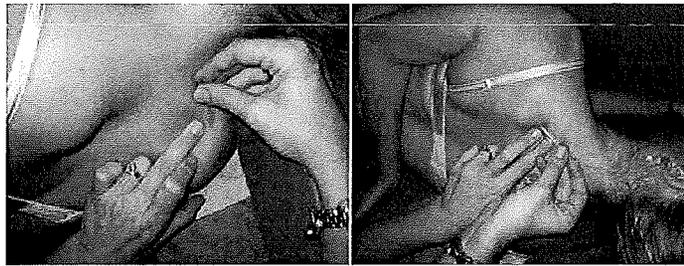


Figure 3 Needling levator scapulae by winging the scapula off the chest wall in side lying with the ipsilateral arm elevated or alternatively the patient lies on their contralateral side with their ipsilateral arm held behind their back. Note: Do not attempt to needle the origin of levator scapulae if the medial border of the scapulae is not able to wing off the chest wall.

by their side, hanging over the side of the bed or elevated onto the bed next to the patient's head. If the acupuncture needle is left *in situ*, the patient should be advised that they can only move their arms upwards towards a flexed shoulder position if they need to change the position of their arms as this assures that the needle angle will not change to point in a caudad direction (Fig. 4).

Acupuncture Training and Continuing Education

Prospective studies and retrospective surveys have determined that acupuncture and dry needling is very safe in the hands of competent practitioners who have completed adequate training programs.³⁸ It has been suggested that adequate competency-based training with regard to safety in acupuncture and dry needling minimizes foreseen adverse events.^{11,28,66} Educational levels and continuing professional development requirements are currently the subject of intense debate;⁶⁶ however, case study reviews involving needle penetration to pleura or pericardium suggest that poor practitioner judgment in terms of needle depth penetration, needling technique, and relevant anatomical knowledge is at times linked to iatrogenic pneumothorax.^{37,62} Clinical regulatory bodies should uphold professional standards and reinforce continued professional development requirements for needling vulnerable areas with such standards affecting qualified practitioners, educational bodies, and professional organizations.

Summary

The risks associated with the use of acupuncture and dry needling in the thoracic region warrant consideration in view of the growing number of physiotherapists and other health practitioners globally using these techniques. Extra care should be taken when needling patients with conditions or risk factors that have been associated with primary or secondary spontaneous pneumothorax such as COPD, lung cancer, RA, AS, SLE, sarcoidosis, Marfan's syndrome, a tall slim build, cortisone therapy, or in smokers. Any presenting signs and symptoms of a primary or secondary pneumothorax should alert the practitioner who is considering treating a patient to assess further with chest auscultation, percussion, and X-ray and referral for urgent medical management if indicated.

Iatrogenic pneumothorax relating to acupuncture or dry needling is very rare and the risk of related mortality is extremely remote. Safer techniques include needling dermally or in an acutely oblique direction over bony skeletal structures, or where possible lifting the muscle and soft tissue to be needled away from the chest wall and needling away from the underlying lung tissue. Acupuncture and dry needling administered by well-trained physiotherapists and other medical practitioners is very safe; however, to maximize safety, therapists should not perform advanced acupuncture and dry needling techniques in vulnerable areas, such as the thoracic



Figure 4 Angle of inclination alters with arm position when the needle is left *in situ* in upper trapezius (Gall Bladder 21). A degree of cephalad obliquity should be maintained at all times and patients should be advised that they can alter their arm position only by elevating their arms.

region, without completing adequate training by recognized educational bodies.

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Lonny Jarrett M.Ac., FNAAOM

Stockbridge Health Center

To whom it may concern,

I'm writing to express my concerns regarding allowing physical therapists to perform "dry needling" in Massachusetts. I have practiced Chinese medicine for 25 years, written two of the leading texts in the field, am a founder of the Acupuncture and Oriental Medicine Society of Massachusetts, and am on the continuing education faculty of many schools of Chinese medicine internationally (resume enclosed). Additionally, I hold a masters degree in Neurobiology and, in 1982, did my masters presentation on the neural innervation of trigger points and the relationship of these points to acupuncture. Trigger points were first needed during investigations of referred pain associated with angina and studies of rheumatism in the late 1940's and early 1950's. Scientists soon noticed that pain relief occurred even with the placement of "dry needles" without the injection of anesthetics.(1) What seemed to be important was the location of needle placement. In some of the studies it was commented that not only was needling effective for pain relief but that results warranted investigating if the technique of "dry needling" actually was evidencing improvement in the underlying conditions.

Concurrent with Nixon's trip to China in 1972 James Reston, columnist for the Washington post, underwent an appendectomy and received acupuncture for his postoperative pain. His report in the Post aroused the interest of neuroscientists Patrick D. Wall and Ronald Melzack at McGill University i Montreal who were putting forward their "Gate Control Theory" of pain at that time. They noted a high correlation (71%) between the location of acupuncture points and trigger points in much of their research (2) and even a higher correlation (97%) has been noted in recent studies (3).

While the Trigger point studies note only the use of points for pain relief, the high correlation in location and similarity of technique makes it clear that placing needles in, or near, acupuncture point locations and on meridian pathways precisely mimics the practice of acupuncture at a technical level. By licensing acupuncturists and holding them to a strict and rigorous standard of study and practice the state of Massachusetts has recognized the serious medical implications, and necessary study warranted, for performing such a technique. Physical therapists receive no training in the deep medical implications of needling the points that they use so they posses little context regarding the broader implications of their actions on physiology. This can potentially lead to serious consequences for patients. Beyond that is the concern that allowing "dry needling" will open up the door for PT's to take a weekend class, perhaps read a few books, and haphazardly mix the complex concepts and technology of Chinese medicine with their own practice in a way that compromises the practices of Chinese medicine, physical therapy, and the well being and health of the patient.

To sum, acupuncture by any other name is still the practice of a complex medicine that requires years of study to practice safely. It is my strong recommendation that the interests of the citizens in the state of Massachusetts would be best protected by confining the use of acupuncture needles therapeutically to licensed acupuncturists and MD's.

Sincerely,

Lonny Jarrett

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Chapter 4.2

Peripheral Nerve and Muscle Stimulation

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Abstract

In this chapter we focus on technology to activate electrically peripheral motor nerves. Two important concepts are stressed; 1) the closer the electrode is to the target tissue the easier it is to isolate the applied electric field to a smaller region and 2) the affect of the applied electric field is, generally speaking, always the greatest on the largest myelinated axons experiencing the applied electric field. . These concepts are applicable to other neural systems.

Motor nerves can be activated through electrodes placed on the surface of the skin, on the surface of the muscle, in the muscle, on the motor nerve or in the motor nerve. All electrodes must satisfy the requirements of material compatibility, mechanical compatibility and the ability to transfer the required electrical charges without tissue or material deterioration. The choice of electrode materials and geometric design are determined by these factors and by the intended location on the nerve or muscle. Specific designs, tissue reactions and applications are described herein. Electrodes placed on muscles produce single muscle activation. Nerve electrodes can have the advantage of activating multiple muscles. Selective stimulation of peripheral nerve fibers for effecting specific muscle activation or specific motor function is discussed in the section on nerve electrodes.

1. Introduction

The material presented in this section will focus on electrodes that can be used to activate motor nerves electrically. There are three basic locations where electrodes are applied for this purpose, on the surface of the skin (surface electrodes), on or in the muscle (epimysial or intramuscular electrodes), and on, in or adjacent to a nerve trunk (these are often thought of as nerve cuff electrodes). The reason for choosing the motor system and

muscle as the target organ is the simplicity of the system and the fact that the output of the motor system is easily measured.

At the peripheral level, the motor system is comprised of a nerve fiber, one highly efficient synapse per muscle fiber, and the set of muscle fibers ("motor unit") that connects to tendon and bone, and to which force and position transducers can be easily applied to measure the behavioral response. Because of the highly efficient nerve-muscle synapse, a single evoked propagating action potential will result in a measurable force when the motor axon is excited.

Other behavioral systems that could be and should be of interest are those controlling sensory perceptions, such as visual and auditory, or even feelings such as pain and emotional distress. Unlike the peripheral motor system, these systems usually involve multiple synapses between the activated nerve and the behavioral response, the synapses in these systems are not as efficient, and the behavioral response, a perception or feeling, is not easily measured or quantified. In these non-motor systems a single evoked propagating action potential may not result in a detectable response. Even though the target organ in this presentation is muscle, the concepts are applicable to other body systems that present similar nerve-tissue-electrode environments but where the evoked response is something other than a measurable force or movement.

2. Basic Concepts

A rule of thumb to keep in mind is that the effects of an applied electrical field are always greatest on the larger diameter axons and the axons closest to the electrode. The effect can be either depolarization or hyper polarization.

Nerve Depolarization/Excitation: When the transmembrane potential is decreased to a level that a sufficient number of voltage gated sodium ion channels are switched from the resting-excitabile state to the active state it causes a propagated action potential to be initiated (see Chaps. 1.1 and 2.1). This state change occurs when the net transmembrane current is positive, flowing from the inside of the cell to the outside of the cell, and is usually caused by the application of a cathodic stimulus applied near the site of excitation.

Nerve Hyperpolarization: When the transmembrane potential is increased from the resting state, the voltage gated sodium ion channels are less likely to be gated into the active state and the population of voltage gated ion channels that were previously inactivatable can be switched to an activatable state. This state change occurs when the net transmembrane current is negative, flowing from the outside of the cell to the inside of the cell, and is usually caused by the application of an anodic stimulus applied near the site of hyperpolarization.

Virtual Cathode: A site that is some distance from the actual electrode, usually the electrode designated as the anode, where the net transmembrane current is positive,

positive charge flows from the inside to the outside of the membrane, the transmembrane potential is lowered, and nerve excitation can occur (Fig. 1).

Virtual Anode: A site that is some distance from the actual electrode, usually the electrode designated as the cathode, where the net transmembrane current is negative, positive charge flows from the outside to the inside of the membrane, the transmembrane potential is increased, and nerve hyperpolarization can occur (Fig. 1).

Motor Point: A site, usually on the surface of a muscle, but can also be used to indicate a position on the skin or a point within the muscle, where the amplitude of the stimulus required to fully activate the muscle is at a minimum. Physically, this is a site where all of the motor nerve fibers are closest to the stimulating electrode.

Denervated Muscle: A muscle that has lost its motor neuron innervation. The mechanism by which nearly all motor prostheses work is by electrically activating the motor nerves that in turn synaptically activate the muscle fibers of each motor unit served by the activated motor nerve. If the muscle fibers were to be activated directly from the applied stimulus, the externally applied field would have to be sufficient over all muscle cells for all to be activated. Without the benefit of nerve fibers distributing the action potential and the amplification effects of the nerve-muscle synapse, the applied stimulus may cause injury to the cells close to the electrode before the electric field in the region of the most distant fibers was above threshold in all but the smallest muscles of the body. The strength-duration curves for indirect, via motor nerve, and direct muscle activation are shown in Fig. 2⁴⁴.

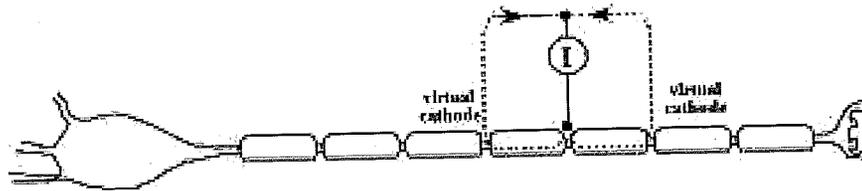


Fig. 1. Schematic representation of nerve and an external stimulator with an electrode positioned on a node of Ranvier. The stimulus shown is anodic. Positive charge enters the nerve under the electrode and exits the nerve at adjacent nodes. Current exiting the nerve membrane gives rise to membrane depolarization. Current exiting the nerve membrane at a site removed from the actual electrode is termed a virtual cathode. Current entering the nerve membrane, causing hyperpolarization, at a site removed from the actual electrode is termed a virtual anode.

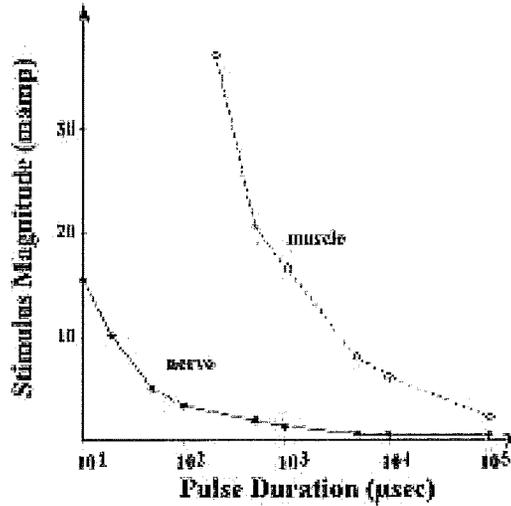


Fig. 2: Strength-Duration curve for nerve and muscle tissue. Data were acquired with intramuscular electrodes placed in cat tibialis anterior muscle. The evoked muscle response was constant throughout the tests at a submaximal level. Curare was administered to achieve the direct muscle activation response. After Figure 20 in Mortimer (Mortimer 1981)

Activating Function: When an extracellular stimulus is applied to excite a nerve, mathematical models predict that the second difference quotient of the extracellular field is the driving force to cause membrane depolarization or hyperpolarization (see Chap. 2.1). In the simplest form the following equation applies to a myelinated nerve fiber with its long axis along the “x” axis ⁴¹.

$$\frac{V_{e,n-1} - 2V_{e,n} + V_{e,n+1}}{\Delta x^2} \quad (1)$$

Where $V_{e,n}$ is the extracellular potential at the n th node of Ranvier, $V_{e,n-e}$ is the extracellular potential at the node immediately to the left of node “n”, and $V_{e,n+1}$ is the extracellular potential at the node immediately to the right of node “n”. This equation indicates that the driving function is greatest in regions where the potential gradient is the steepest.

Electric Potential in Tissue Medium: To a first approximation, the stimulating electrode is considered to be a point source, the tissue medium is homogeneous and isotropic and the electric potential at any point in the tissue medium can be calculated from:

$$V_e = \frac{\rho_e I_{stim}}{4\pi r} \quad (2)$$

Where “r” is the distance from the point electrode to the point in tissue space of interest.

Perineural Membrane: The perineural membrane is an extension of the dura in the spinal cord and surrounds or bundles axons coursing in the periphery. This membrane helps to maintain an extracellular medium surrounding the axons that is different from that found in other tissue in the peripheral portions the body.

Anodic Break Excitation: A nerve appears to self-generate an action potential following the release of a hyperpolarizing (anodic) pulse. The effect of the hyperpolarizing pulse is to elevate the excitability of a nerve by activating previously inactivated voltage gated sodium ion channels or in terms of the “m” and “h” parameters of the Hodgkin-Huxley model of a nerve, “h” is increased from ~0.6 to values at or close to 1.0. Increasing “h” reflects a larger percentage of the sodium ion channels have been put into the inactive-activatable state that were in that state under resting conditions. When a large number of these channels become active just after the release of the stimulus, sufficient current can flow to induce a propagated action potential.

3. Electrodes Placed on the Skin Surface

3.1. Introduction

Surface stimulation was used for the earliest applications of electrotherapy. The Roman physician Scribinus Largus is said to have advocated the electrical discharge from the Torpedo fish for relief of pain⁴⁰. In the eighteenth and early nineteenth centuries, surface electrical stimulation was applied to alleviate various ailments²⁸, reinforcing any mystical beliefs one might have about electricity.

Electrodes applied to the surface of the body usually consist of a metal plate with an electrolytic gel to maintain contact. Common materials are stainless steel, silver-silver chloride, platinum or gold plated surfaces. These electrodes are often discoid in shape, but other geometries, conforming to the body contour, are also in use. Many electrodes are self-adhesive or are strapped onto the body surface. Suction electrodes, similar to ECG electrodes are also used. Flexible electrodes made of carbon filled silicone rubber or conductive polymers are also available.

Changes in the surface conditions of the skin and differences in positioning of electrodes can lead to variability in stimulation characteristics. As a non-invasive means for temporary electrotherapy, these electrodes provide ease of application and do not need extensive operator skills.

3.2. Applications to the motor system

3.2.1. Lower Limb

Surface electrodes have been used to assist ambulation for paralyzed subjects. A number of different systems have been developed for clinical use. WalkAid was designed at the University of Alberta, for the management of foot-drop, where subjects are not able to make their toes clear the ground during the swing phase of walking. WalkAid is adjusted by a tilt sensor, which determines threshold angles for turning stimulation on and off⁷⁸. The Odstock Dropped Foot Stimulator (ODFS) was developed in Salisbury, UK between 1989 and 1995. It is a single channel stimulator for drop-foot correction during walking using self adhesive skin surface electrodes placed on the side of the leg. A two channel stimulator O2CHS was later used. The devices are controlled by a foot switches to synchronize stimulation^{13, 70}. MikroFES was an orthotic stimulator for correction of drop-foot in paralyzed subjects designed at Lubjiana, Slovenia,⁶.

Surface stimulation has been used in conjunction with orthoses for assisted walking. The HAS (Hybrid Assist System) applied surface stimulation with an externally powered brace⁵⁵. The RGO system is a walking device that uses surface electrodes and passive bracing⁶⁷. By way of historical credit, Liberson³⁶ developed the first drop foot brace and Kantrowitz³² was the first to report paraplegic standing

3.2.2. Upper limb

Surface electrodes have been used to restore grasp in upper extremity paralysis. The Handmaster was initially developed as an exercise device in Israel for activation of the hands of subjects with C5 spinal cord injury. It uses surface electrodes in a forearm-wrist splint to stimulate the paralyzed muscles⁶⁶. It uses a push button switch and a sliding resistor to adjust hand position. The BGS (Belgrade Grasp System) was developed by Popovic to provide for hand grasp and arm reach. It used a separate channel to activate the triceps muscle to provide shoulder reach. The Bionic Glove was designed for subjects who have active control of wrist flexion-extension. It uses a position transducer mounted on the wrist for stimulation control^{54, 56}. A similar device controlled by EMG from wrist extensors has also been described⁶¹. By way of historical credit, Long was the first person to report electrically induced hand grasp³⁷.

3.2.3. Scoliosis

Surface stimulation has been investigated as a treatment for scoliosis (lateral curvature of the spine^{4, 11}. Paraspinal muscles were activated, typically during the night, for curvature correction. Retrospective studies appear to show that the outcomes with electrical stimulation were not significantly different than the natural progression of the

spinal curvatures. It was not found to be effective in preventing curve progression for idiopathic scoliosis in a group of 30 adolescents²². A prospective study comparing the outcomes of bracing and electrical stimulation with untreated patients did not show improved results with those treated by electrical stimulation⁴⁶.

4. Electrodes Placed In or On the Muscle

Electrodes placed beneath the skin can be positioned closer to the target motor nerves than an electrode on the surface of the skin, and uncomfortable sensations that are associated with activating cutaneous sensory fibers can usually be avoided. Positioning the electrode close to the target muscle also lessens the likelihood of spillover excitation, i.e., activation of non-target muscles. Two classes of electrodes are considered under this heading, intramuscular electrodes and epimysial electrodes. Both electrode types are in direct contact with the muscle but separated by muscle tissue from the motor nerves innervating the muscle.

Considering that the excitatory potential decreases inversely with the separation between the electrode and motor nerve, the electrode should be positioned at a point that is close to the region of the muscle where the major portion of the motor nerve fibers are located. This position or point is often referred to as the "motor point". At the "motor point", the stimulus amplitude required to fully activate the muscle is at its lowest value. In the case of the epimysial electrode, the motor point can be identified by moving a stimulating electrode across the surface of the muscle to locate the surface position that requires the least amplitude to fully activate the muscle. In the case of the intramuscular electrode, a fine needle probe might be used by itself or in conjunction with a surface probe; the "motor point" for an intramuscular electrode is usually just below the muscle surface at the "motor point" position identified with a surface electrode.

For most if not all practical neural prostheses, muscle activation, is through electrical depolarization of the motor nerve and not direct depolarization of the muscle membrane. Even though muscle cells contain voltage gated ion channels, generate propagating action potentials, and are electrically excitable, the stimulus amplitude required to activate a muscle directly is very much greater than that required to activate muscle indirectly, through its nerve supply (see Fig. 2).

In skeletal muscle, as opposed to cardiac muscle, muscle cells are activated, directly by the applied stimulus or through their nerve supply rather than by propagation from adjacent muscle cells. Therefore, for direct muscle activation the stimulus level must be sufficient to activate all muscles fibers of interest, which is usually all of the muscle cells in the muscle. Because the electric potential decreases inversely to the separation between the electrode and target cell, very large stimulus amplitudes are required to activate directly muscle cells only a few millimeters away from the electrode. These amplitudes can easily be in excess of values considered to be noninjurious for all but the

smallest muscles. For this reason, motor prostheses are considered practical only for muscles that retain their motor innervations.

4.1. Intramuscular electrodes

4.1.1. Introduction

Intramuscular electrodes are relatively easy to implant, particularly those having a percutaneous lead that can be inserted with a hypodermic needle. These electrodes first made their appearance in the later part of the 1960's as an extension of intramuscular recording electrodes⁷. The recording electrodes were insulated straight wires, usually in the 25 to 50 μm diameter range, with short deinsulated portions at or near the ends of the wires to sense the potential changes caused by propagating action potentials in the muscle. The electrodes were loaded into a hypodermic needle with only a bent tip outside the needle to act as a barb that would catch in the tissue when the needle is withdrawn.

These electrodes had a life expectancy of a few hours to a couple of days. The failure mode of these electrodes was mechanical fatigue resulting from repeated bending as the muscle moved during contraction. A recording electrode was easily converted to a stimulating electrode by replacing the external recording amplifier with a current or voltage pulse generator. To extend the life expectancy of these intramuscular electrodes the straight wire was coiled into a helix, which transforms a bending force on the electrode into a torsional force on the wire¹⁵. In the helical configuration the life expectancy of these electrodes were extended to about one month.

Longevity of these electrodes was further extended when the electrodes were fabricated with stranded, insulated wire, usually seven strands with each strand in the 30 μm diameter range. The insulated stranded wire was wound into a helix with the tip deinsulated and bent to construct a barb that would catch in the muscle tissue, holding the electrode in place when the hypodermic needle was withdrawn. These electrodes had a life expectancy of a year or so. Subsequent modifications to the barbed helically wound intramuscular electrode design have been to wind a pair of stranded wires in tandem. The open helix configuration was preserved in the Peterson version⁵³ and a closed helix version was created (helix enclosed in silicone rubber tubing), known as the Memberg electrode⁴³. Both of these versions exhibit life-times that appear to be twice or more that of an electrode wound from a single stranded wire (personal communication and⁵⁷). A review of intramuscular electrodes and their development can be found in the first chapter of Bhadra's master's thesis⁸.

4.1.2. Materials and Construction

The strength, flexibility and tolerance of mechanical deformation are important considerations in the design of intramuscular electrodes. The stimulating surface and the lead sections of these electrodes are often one continuous metal. They are usually fabricated by stripping off the insulation from an insulated wire to provide for the stimulation interface. The whole wire is then formed around a wire mandrel to fabricate a stimulating tip and lead in one operation. These electrodes are usually implanted in the body of the muscle using a hypodermic needle as a carrier for the electrode with the body of the electrode loaded in the hypodermic needle prior to implantation. The electrode is usually unloaded from the hypodermic needle when a barb, attached to the electrode, remains outside the hypodermic needle, catches in the tissues as the hypodermic needle is withdrawn. Scheiner et al,⁶³ used a small rod in the center of the electrode rather than a barb to unload the intramuscular electrode.

The "barb", for many of the electrodes that have been used, is a portion of the wire bent backward that forms the stimulating tip and the lead. Exceptions to this "barb" configuration include polypropylene barbs used with the Peterson and Memberg electrodes and metal wire barbs were used with the Scheiner electrode⁹. The "barb" serves as an aid to unload the electrode from the hypodermic needle and more importantly to stabilize the electrode in the implanted position until the fibrous tissue encapsulates the electrode. The data illustrating the withdrawal force required to dislodge four types of intramuscular electrodes are shown in Fig. 3.

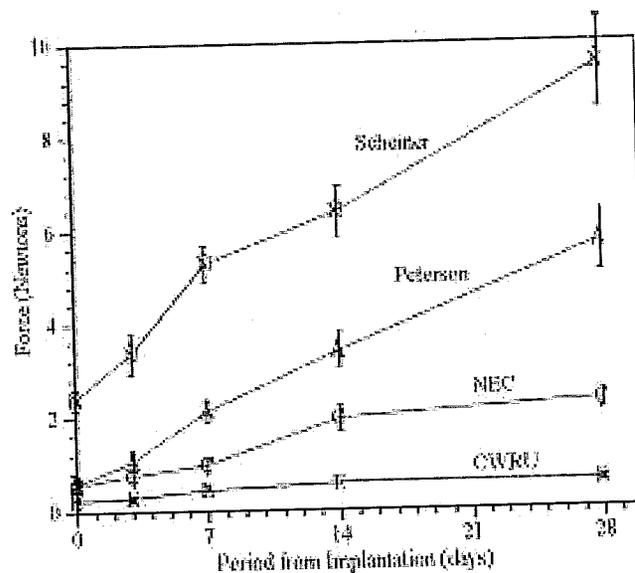


Fig. 3 : Mean and S. E. of the peak force at dislodgement (PFD) for the four types of electrodes in the five implantation periods common to them. The electrode types are described in (Bhadra 1993).

From Fig. 3 it can be seen that the force required to dislodge an intramuscular electrode increases with time after implant, which is attributed to the development of fibrous tissue encapsulation. The fibrous encapsulation does not appear to provide restraint from movement until after the seven days following implantation⁹.

The most common metal used in the fabrication of intramuscular electrodes is 316 LVM stainless steel (low carbon, vacuum melt). Because the metal has an amorphous structure, the likelihood of mechanical failure is reduced at grain boundaries, where high stress concentrations can develop and in very small wires cause conduction failure. The main problem to worry about is corrosion of the electrode if the potential across the electrode-solution interface becomes more positive than +400 mV, referenced to a Saturated Calomel Electrode (SCE)⁴⁵. Platinum is more resistant to corrosion than stainless steel but is more prone to mechanical failure because platinum tends to form "grains", crystals that can become the size of the wire, in the range of 25 μm . Adding iridium to platinum can reduce the grain size but usually the resulting strength of Pt/Ir is below that of stainless steel. Caldwell¹⁴, described a dispersion hardening process and reported that Platinum-Iridium with Thorium added (ThO_2) showed a 50% improvement in yield strength, a value that compares well with that of 304 stainless steel.

4.1.3. Applications to the motor system

Intramuscular electrodes have been employed in a number of devices where a muscle is the target organ. They have been used to activate paralyzed muscles that retain a functional motor neuron in the muscles of the upper extremity⁵¹, lower extremity³⁹, and diaphragm⁵². They have also been used to activate muscles to cause the evoked muscle force to perform functions other than moving a limb. For instance, muscles of the back have been moved to inside the chest and wrapped to form structures that can aid in pumping blood (see Chap. 4.1)¹⁶, and muscles of the leg have been moved and wrapped to perform as a sphincter for maintenance of bowel continence⁵ and urinary continence³¹ (see Chap. 7.4). Muscles have also been stimulated to correct spinal deformity in the treatment of scoliosis³⁰. Such electrodes are able to activate segments of muscles, particularly the deeper ones, in a way that may be difficult to achieve with other kinds of electrodes.

4.1.4. Tissue reaction considerations

The coiled wire intramuscular electrode has been found to be tolerated well by body tissues, in the subcutaneous tissues, and at the sites where the electrode exits the skin,

when the electrode is used as a percutaneous electrode. The tolerance is attributed to the materials used in fabrication and the physical configuration of the electrode.

Figure 4 shows a Peterson electrode. The diameter of the wound insulated portion is approximately 800 μm . The materials used in the fabrication of these electrodes are:

- 316 LVM stainless steel wire forms the conducting lead and the stimulating tip. The wire is stranded from seven strands of wire each strand is 40 μm in diameter.
- Perfluoroalkoxy (PFA) insulation 50 to 75 μm in thickness.
- Polypropylene suture material, 5-0 gage or diameter, forms the barb and center core of the electrode assembly.

The subcutaneous tissue reaction to the Peterson type of electrode is shown in Fig. 5. The tissue was cut in a plane that is parallel to the axis of the electrode ¹⁹. In the left hand panel, the area appearing as an oval hole is the space occupied by the insulated helix portion of the electrode lead. The long oval space in between the oval holes is the space occupied by the polypropylene core. In the right hand panel is the tissue reaction around the stimulating tip/barb portion of the electrode. A higher power view of the region between two windings, indicated by the box in the left hand panel is shown in Fig. 6.

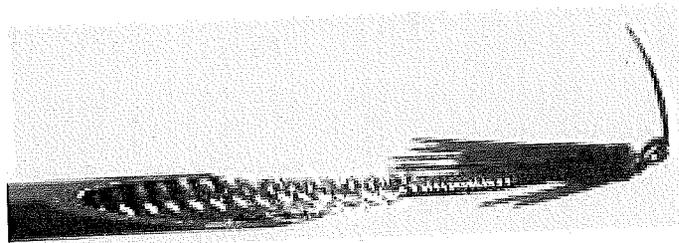


Fig. 4. Photograph of Peterson type electrode. The diameter of the insulated helical portion of the lead is approximately 800 μm . The electrode is shown partially loaded into a hypodermic needle, on the left hand side of the figure.

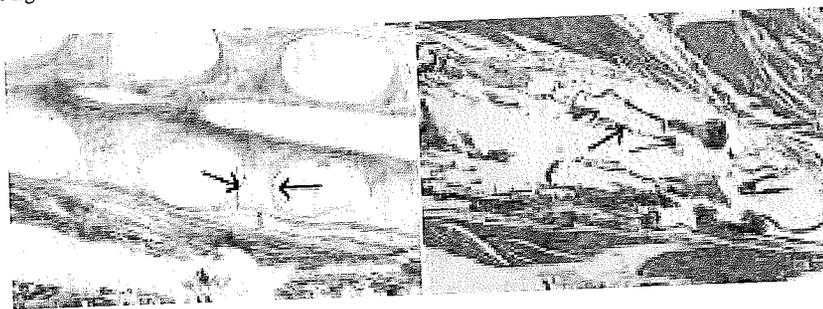


Fig. 5. High power magnification of the tissue encapsulation between two windings of the helically wound lead of the Peterson electrode. At the interface between the electrode insulation and the tissue a compact group of cells forms a barrier between the implant and the interstitial space, indicated by arrows. This barrier layer is in

the range of three to four cell layers thick. The space between the barrier walls contains a loose connection of cells and collagen. From (Corey, 1990).



Fig. 6. Higher magnification view of the encapsulation tissues occupying the space between two coils of the lead wire (left panel of Fig. 5). Adjacent to the insulated lead is a thin layer of cells that are closely packed and believed to for a barrier bacteria. The majority of the connective tissue lying between the two coils is loose connective tissue dominated by collagen fibers.

The tissue reaction to the helically wound lead provides insight into the reasons why these percutaneous electrode leads are so well tolerated in the body and as they traverse the skin. The compact cell layer provides a barrier that suppresses bacterial entry into the tissue spaces and a barrier to nutrients required to sustain bacterial growth in the area occupied by the wound lead. The "open" helix and the loose connective layer permit the lead to extend and compress under axial loads without a piston like action as would occur with a closed cylinder lead under similar loads. A sliding motion between the tissue encapsulation and the lead is believed to irritate the encapsulating cells and discourage the formation of a barrier layer.

Examination of the tissue reaction at the skin exit site shows that the epidermal layer extends down about 3 mm to form a well with a diameter of approximately 1.0 mm, slightly larger than the wound lead. At about 3 mm below the surface of the skin tissue encapsulation begins to form with the characteristic compact layers and loose connective tissue layers. Experience suggests that when the compact layer is disrupted, the tissues become vulnerable to bacterial invasion and infection. Microscopic particulate matter, adhering to the implanted device, will antagonize the formation of the compact cell layer barrier, because of the presence of a chronic inflammatory response to an otherwise sterile implant. To reduce the likelihood of implanting a lead with particulate matter adhering to the surface, a thorough cleaning procedure (see §7) is recommended prior to implantation, and the electrode should be kept immersed in sterile water or saline prior to implantation whenever possible. It is important to keep in mind that a clean polymer surface is often hydrophobic and that particulate matter it comes into contact with will cling to it and possibly be carried into the tissue space at the time of implantation.

Removal of a percutaneous intramuscular electrode, or open helix lead, by pulling on it, involves rupturing the encapsulation tissue layers with little if any disruption of muscle tissue⁸. As the lead is pulled, individual turns of the helix uncoil by tearing the encapsulation layer (Fig. 7). The tearing of successive encapsulation layers continues until the barbed end of the electrode gives way, usually including a few undisturbed coils of the helix. The tearing to the tissue layers usually does not involve muscle tissues. It is important to recognize that if the force applied to the lead wire exceeds the yield strength of the material, the lead will mechanically fail, often below the skin. Further, it is likely that the fractured end is no longer coiled and therefore that uncoiled portion is not as compliant as a coiled helix to axial loads.

Experiments in animals⁴⁵ indicate that the tissue reaction to stimulation is not statistically different from what would occur with a passive implant, provided the charge injection is below $20 \mu\text{C}/\text{cm}^2$ for cathodic monophasic stimuli and $40 \mu\text{C}/\text{cm}^2$ for balanced charge biphasic stimuli. The $40 \mu\text{C}/\text{cm}^2$ for balanced charge biphasic stimuli, cathodic phase first, limit is set by corrosion that can occur during the anodic phase of the stimulus pulse. When imbalanced biphasic stimuli are applied, less charge in the anodic phase than in the cathodic phase, a much larger charge can be injected before evidence of tissue injury is observed⁶².

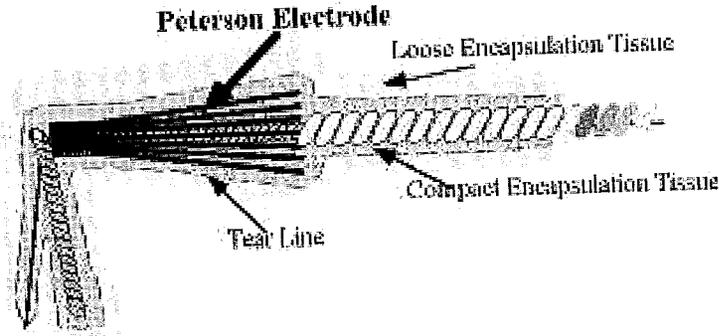


Fig. 7. Schematic drawing of Peterson type electrode, encapsulation tissues and muscle, into which the electrode had been implanted. The lead was pulled to the right for removal (Bhadra 1993).

4.1.5. Side effects

Percutaneous intramuscular electrodes can fail. Evidence of failure is usually gleaned when a stimulus, applied to the terminal end of the electrode lead, fails to result in a physiological response, e.g., muscle contraction. When this occurs within days or a few weeks following implantation the cause is usually electrode movement away from the "motor point" area, but could also be due to a mechanical failure in the lead causing a break in the conduction pathway. If the stimulus current and voltage can be measured, an

open circuit can be distinguished from electrode displacement by excess voltage or a reduced current flow detected upon application of the stimulus pulse. Loss of the stimulus response after weeks or months after implantation is almost always a result of a break in the electrical conduction pathway.

Percutaneous intramuscular electrodes/leads can be removed after long periods of implantation, but care must be taken not to exceed the yield strength of the wire, which is usually the strongest component of the lead. Tension applied to the lead will cause the coiled helix to uncoil, which means that the tissue encapsulation that has formed around the lead tears. When this encapsulation layer has been disrupted, any pathogen barrier that it provided will be lost and the skin exit site is vulnerable to infection. Therefore, it is important to keep the site "free" of bacteria at the time of lead withdrawal and until the site heals, typically several days. If the lead breaks beneath the skin during removal, it is very likely that a portion of the coiled lead will straighten. The straightened portion of the lead may not be as compliant as the coiled portion and unable to compress or extend when the surrounding tissues move relative to each other. Under these circumstances, the straightened portion of the lead may cause continued irritation of the surrounding tissues due to relative movement. This continued irritation of the cells adjacent to the straightened section of the lead may not allow a tight cell layer barrier to develop around the lead. Further, it is possible that the continual relative motion of the straightened lead and surrounding tissues may cause the straightened portion to erupt through the skin. The erupting portion of the lead will not have a well-formed tight cell barrier and will be vulnerable to bacterial invasion and infection. Reddening and slight swelling at the impending eruption site will precede often eruption. If proper caution is not taken to address the erupted portion of the lead, infection may ensue.

Four groups have reported on their clinical experience with percutaneous electrodes. Knutson and colleagues³³ employed electrodes that were of an open helix design and fabricated from multi-filament (7 or 10 strand), FEP Teflon®-insulated, type-316L stainless steel wire with a diameter of approximately 200 µm. The wire was wound around an arbor into a coil, forming an electrode lead with a diameter of approximately 580 µm. They report on 858 electrodes implanted over a period between 1978 and 1998. Their data show that 95% of the electrodes were functional at six months, 91% of the electrodes were functional at twelve months and that 78% of the electrodes survived both the *in situ* period and were extracted whole at six months and 57% survived after twelve months of implantation. Some 16% of their subjects experienced infection or a granuloma at the lead exit site. Knutson and colleagues³³ state "All incidents were localized, non-systemic occurrences and were resolved by administering antibiotics, cleaning the implant site, removing electrodes, cauterizing with silver nitrate, or excising electrodes or granulomas." Smith⁶⁵ and colleagues reported on their experience with similar electrodes used in adolescents with tetraplegia. They report that 75% of the electrodes survived six months and 51% survived one year.

The second group, Prochazka and Davis ⁵⁷, reported on their experiences with a “single wire” electrode that was similar to that used in the Knutson, et al. study and with one that was similar to the Peterson electrode, which is wound with two separate wires and has a Prolene® central core. They reported that five of eleven “single wire” leads failed within eight months. They found that the “Peterson type” electrodes had a longer survival period. Of seven implanted electrodes, four were still functioning after 4.75 years.

The third group, Handa and colleagues ²⁹, have reported that their experience with a “hard” 316L stainless steel wire had a lower failure rate than when they used a “soft” 316 stainless steel base material. Their “hard wire” electrode was fabricated using a “rope” with nineteen strands of 25 µm wire wound into a helix. They report an average failure of less than 2% over a period ranging from eleven to fifty weeks.

The fourth group, Scheiner and colleagues ⁶³, reported on a percutaneous intramuscular electrode wound with a compound helix, which they called a double helix. They reported on 775 electrodes over a five year period. Sixty-five percent (453) served the intended purpose. Seventy-four (10%) of their electrodes failed due to mechanical failure, usually with the first year of service and four (0.5%) were removed because of infection.

4.2. Epimysial electrodes

4.2.1. Introduction

Epimysial electrodes are electrodes positioned on the surface of a muscle, below the skin and not in the muscle. These electrodes are usually secured to the muscle by sutures or staples and are insulated on one side to direct the stimulus current away from non-target tissues, e.g., sensory nerve fibers in the skin or adjacent muscles. A perceived advantage of epimysial electrodes over intramuscular electrodes is that they (electrode and lead) are less prone to mechanical failure and less likely to move in the hours/days immediately following implantation.

When using epimysial electrodes there are two important points to consider: electrode location relative to the motor nerve, and movement of the electrode relative to the underlying tissues when the muscle changes length. Grandjean and Mortimer ²⁶ reported on work carried out in the calf muscles of cat. The results of this work indicated that when a monopolar epimysial electrode was closest to the motor nerves:

- Threshold stimulus amplitude was lower;
- The gain was the highest, that is differences between the threshold levels of activation and full activation were small;
- The selectivity was the greatest in that a larger portion of the target muscle could be activated before the amplitude was sufficient to activate nearby muscles;

- Length dependent recruitment was minimized, that is the percent of the muscle activated at a given stimulus magnitude changed the least as the muscle lengthened from the shortest to the longest muscle length.

When a bipolar epimysial electrode is used rather than a monopolar electrode with a distant return electrode, the stimulus current is constrained to regions closer to the two electrodes. Compared to the results with the monopolar electrode:

- Threshold was increased;
- Relative gain decreased;
- Greater selectivity was found in the range closer to threshold and poorer selectivity was present in the stimulus range closer to maximum activation of the muscle.

4.2.2. Applications to the motor system

Epimysial electrodes have been used by Hunter Peckham and colleagues for a number of years in their development of an upper extremity assist device for C5 or C6 adult subjects with tetraplegia, which became known as the "FreeHand System™" produced by NeuroControl Corporation in Cleveland, Ohio,⁵⁰. This device used epimysial electrodes and Memberg type intramuscular electrodes. The grasping function provided by the device was shown to offer them an improved level of independence and the device is considered reliable with most of the subjects using it at home on a regular basis (see Chap. 6.2).

4.2.3. Tissue reaction considerations

Two groups have reported on the nature of the tissue encapsulation surrounding epimysial electrodes. Akers et al. 1997² reported on an epimysial electrode, formed with a platinum disk embedded in silicone rubber, that is sutured to the surface of the muscle in the leg of a canine and one that is like those used in the "FreeHand System". Their results indicated a mean thickness for the encapsulation layer of 0.179 mm with the encapsulation layer thickening when the attachment sutures were not in place. Schmit and Mortimer⁶⁴ reported somewhat different results for their experiments carried out with epimysial electrodes stapled to the abdominal surface of the canine diaphragm. The tissue capsule forming on the back side of the electrode, a silicone rubber surface facing away from the muscle, was quite thin or not detectable. On the surface between the stimulating surface and the muscle the encapsulation layer had a mean thickness of 1.24 mm. This layer exhibited two subregions, a collagen outer layer and a layer of granulation tissue adjacent to the electrode surface. The nature of the granulation tissue layer suggested the cause was a chronic mechanical irritation brought about by relative

movement between the contracting (shortening) muscle tissue and the non-compressible silicone rubber of the electrode carrier.

4.2.4. Side effects

Schmit and Mortimer reported that relative movement between the contracting (shortening) muscle tissue and the non-compressible silicone rubber of the electrode carrier could result in a transient loss of induced muscle contraction⁶⁴. As the muscle was induced to shorten, the electrode carrier would accommodate the change in space between the two stapled portion by buckling, pulling the recessed disk away from the muscle tissue and subsequent loss of contact. The outward manifestation of this phenomenon was like a brief hiccup with each electrically induced muscle contraction. Replacing the recessed metal disk with a protruding hemisphere solved the transient loss of electrical contact problem.

5. Electrodes Placed On or In the Nerve

Positioning the stimulating electrode on or in the nerve opens opportunities for a degree of selective activation that is not possible with electrodes that are placed in or on muscle or on the skin. Further, the stimulation contact is closer to the target tissues, which means that threshold stimulus currents can be lower, the activating function is greater, and there is a lower demand on the power requirements of the stimulator. Two electrode configurations will be considered; the first utilizes electrical contacts placed on the surface of the nerve, outside the perineural membrane and housed in a silicone rubber carrier, commonly referred to as cuff electrodes, and the second utilizes contacts placed below the perineural membrane, commonly referred to as intrafascicular electrodes.

5.1. Cuff electrodes

5.1.1. Introduction

Cuff type electrodes hold the stimulating contacts in close proximity to the nerve trunk. Holding the target tissues close to the stimulating contacts offers opportunities for power efficiency and improved selectivity. Power efficiency is improved because less power is spent on electrical conduction through the space between the electrode and target tissues. Improved selectivity is possible because the electric potential gradient is larger when the spacing between the stimulating contact and the target tissue is the least. Further, cuff type electrodes are less likely to move in relationship to the target tissues after implantation. In order to take full advantage of these opportunities, it is important that

the electrode assembly be in close contact with the nerve trunk. However, when the cuff is in close contact with the nerve at the time of implantation, there is a risk that blood flow can be compromised and/or the nerve fibers can be mechanically traumatized.

5.1.2. Cuff diameter to nerve diameter ratio

Prior to the 1990s, cuff electrodes were rigid cylinders containing metal contacts embedded in silicone rubber or a similar material, see Naples *et al.* ⁴⁹ for a review of cuff electrodes. The dogma that persisted in the neural prosthesis community was that the internal cuff diameter should be 50% larger than the external diameter of the target nerve, (CNR = 1.5). Implicit in this statement is that the nerve has a round cross-section. This conclusion was based on nerve repair studies performed on transected nerves in the 1960's ²¹. The results of the study indicated that nerve fiber regeneration success was better for nerves that were rejoined when the two ends of the nerve were held in place by a cylinder, with an internal diameter that was 50% larger than the nerve. The perceived importance of the larger diameter was that a cuff with a CNR of 1.5 could accommodate swelling without occluding blood flow in the region of the cuff.

In the 1980's the Huntington helix ¹ was introduced as an alternative design to the rigid cylinder. The concept of the Huntington Helix is illustrated in Fig. 8. Shown here is an early version, which has more wraps than those that are now in use. Stimulating contacts are exposed metal sections along the internal diameter of the helix. The open helix design can accommodate some swelling without constraining blood flow, allowing axial flexibility and compressive/tensile loads. A version of the Huntington Helix electrode is used on the vagus nerve stimulating device marketed by CyberonicsTM (www.cyberonics.com). The recommended CNR for the Huntington Helix electrode is a loose fit such that the lumen of the electrode and the diameter of the nerve are a close match with no constriction of the nerve (personal communication with D.B. McCreery). Installation of the helical configuration can be perceived as demanding for the surgeon. The task is made less demanding by reducing the number of wraps. With fewer wraps there is a risk that the helix will come off of the implanted nerve during body movements; so suturing the helix to the epineurium has been used to reduce the likelihood of accidental displacement in the time immediately following implantation.

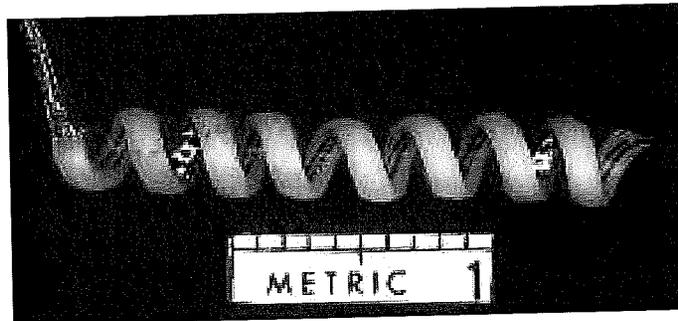


Fig. 8. Photograph showing an early version of a bipolar Huntington helix electrode. Subsequent designs use fewer wraps and a straight section, rather than wraps, between the stimulating contacts. Stimulating contacts can be seen between the ends of the first and second wraps, counting from the left hand side, and the sixth and seventh wraps.

The self-sizing spiral cuff (Fig. 9) also appeared in the 1980's as an alternative to the rigid cylinder⁴⁸. The spiral configuration is achieved by laminating two sheets of silicone rubber together, with one of the layers stretched in relationship to the other. The stretched layer forms the internal aspect of the cuff. Increasing the relative stretch produces a cuff with a smaller internal diameter. Stimulating contacts are embedded between the outer, unstretched, layer and the inner, stretched, layer prior to lamination. Experiments in cats indicate that these cuffs can accommodate CNR between 0.6 and 2.0³.

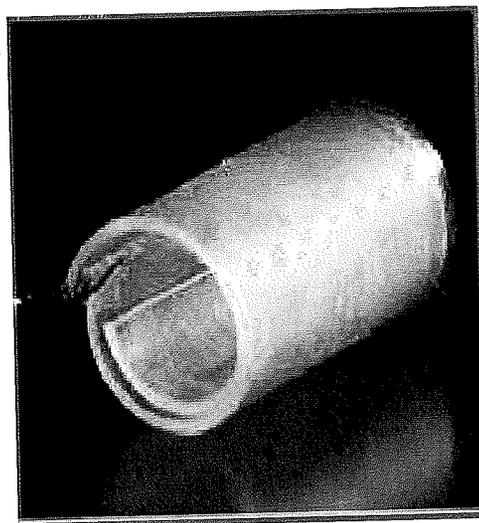


Fig. 9. Photograph of the self-sizing spiral cuff electrode. The spiral configuration can open or close to accommodate a range of different diameter nerves.

Cuoco and Durand²⁰ reported that the measured compressive forces, developed by self-sizing spiral cuff electrodes, were not sufficient to occlude nerve blood flow inside the cuff. The estimated occlusion pressure is estimated to be ~ 27 cm H₂O. These studies were carried out in cuffs that contained no contacts or wire. Care must be taken when routing the lead wire to this electrode to avoid placing a load on the cuff that is sufficient to pull the cuff off of the nerve following implantation. It might be tempting to think of tying a suture around the cuff to avoid accidental displacement, but this would defeat the self-sizing property of the configuration. It can be argued that if the routing of the lead would result in a force applied to the cuff sufficient to displace the cuff from the nerve, it would be better for it to be displaced rather than cause injury to the nerve by mechanically loading it.

Tyler, 1999,⁷¹ reported on an alternative electrode configuration where the effort was to flatten the peripheral nerve. The intent was to align fascicles into a single layer of nerve bundles spaced cross sectional area of the electrode (Fig. 10). The idea, which was considered daring at the time, grew from an experiment where fascicles were found to have been accidentally divided when a self-sizing spiral cuff was displaced after the implant site had been closed³. The results show that the “flattening” effect of the electrode can be tolerated provided the flattening is not too extreme. The upper limit to “flattening” seems to correlate with forces that are great enough to flatten single fascicles.

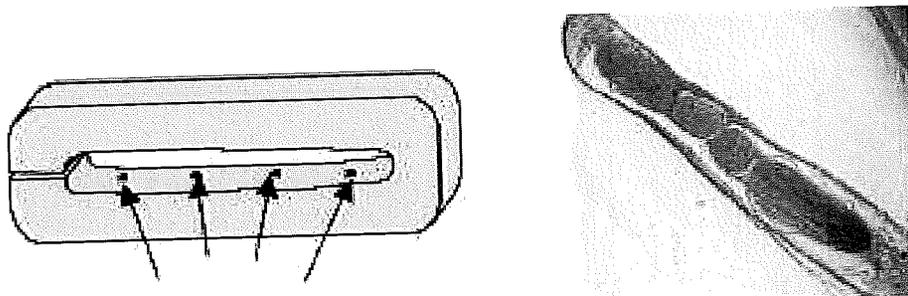


Fig. 10. Schematic drawing of FINE electrode and photograph of rat sciatic nerve after implantation of FINE electrode. The arrows on the left hand figure call your attention to the stimulation contacts, which may be in a position to activate only a single fascicle (Tyler 1999).

5.1.3. Tissue reaction considerations

Tissue reaction considerations include trauma to axons as well as the nature and extent of the encapsulation tissue surrounding the implant. Traumatized axons may not conduct propagating actions potentials and thick encapsulation layers degrade electric field gradients by increasing the separation between the electrode contacts and target axons.

Trauma to axons can be a direct result of mechanical trauma or a secondary effect of loss of blood flow, ischemia⁶⁰. Rydevik and colleagues make a strong point of the effects of compression and stretching on occlusion of blood flow in the vascular bed associated with peripheral nerves. Naples *et al.*⁴⁹ point out that signs of past trauma are often observed in nerves that have received cuff type electrodes. The typical histologic signs take the form of crescent shaped regions containing thinly myelinated axons, which are believed to be remyelinated axons, and greater space between axons occupied by connective tissue. Most of these data come from animal experiments and observable evidence of axon trauma in these studies apparently is rarely noted. Human subjects, who have undergone surgical procedures that involved mobilization of a peripheral nerve, not uncommonly report transient alteration of tactile sensation or muscle weakness. The transient loss of neural function and remyelinated axons are presumed to be characteristics of a transient loss of nerve conduction due to loss of myelin subsequent to a transient episode of localized ischemia. Data acquired by these authors combined with data reported by the group at HMRI indicate that there is a 30% chance that the process of dissecting the nerve free of surrounding connective tissue will cause a transient loss of conduction. The cause of conduction loss appears to be demyelination of axons, believed to be secondary to a transient loss of blood flow that was induced during dissection. When the demyelinated axons are remyelinated, the thickness of the myelin is thinner and conduction returns. These findings are consistent with the report by Larsen *et al.*, 1998,³⁴ where it was concluded, "their implanted cuff electrode may cause an initial loss of axons with subsequent complete structural regeneration".

Thick layers of encapsulation (connective) tissue may degrade the electric field gradient (the activating function), which decreases the possibility of selectively activating small regions of the nerve inside the cuff. Connective tissue forms around an electrode and usually fills all available space. Therefore, loose fitting electrodes will have thicker layers of connective tissue between the cuff and the nerve. A second cause of thick encapsulation is mechanical irritation caused by continued relative motion between the cuff and the surrounding tissues. Sustained mechanical irritation can cause injury to delicate capillaries forming in connective tissues, which can exacerbate connective tissue thickening. To minimize the likelihood of sustained mechanical irritation, the cuff and the nerve should be bound closely together. So-called half-cuffs, cuff configurations that do not completely enclose the nerve, are prone to having thicker layers of connective tissue ingrowth between the nerve and the electrode than do cuffs that completely encircle the nerve. An example of the tissue encapsulation found surrounding a "half-cuff" is shown in Fig. 11.



Fig. 11. Cross-section of the connective tissue formed around a "half-cuff". The horseshoe shaped region in the upper part of the photograph, which is absent tissue, is the space previously occupied by the "half-cuff". The oval shaped region in the lower part of the figure is the nerve, which has been pushed out of the cuff. Close inspection of the upper portion of the connective tissue on the inner aspect of the cuff reveals layers, like rings on a tree trunk. These layers of connective tissue are presumed to have developed in response to mechanical irritation between the cuff and the local tissues.

5.1.4. *Selective activation techniques*

5.1.4.1 Introduction

Ordinarily, when a short duration stimulus pulse is applied to an axon, action potentials propagate from the site of stimulus in both the orthodromic and the antidromic directions (Fig. 12). Cuff type electrodes can be used to effect a degree of selective activation, selectivity, that is not achievable with other configurations. Specifically, action potentials can be created that propagate in only one direction from the site of their initiation, antidromically or orthodromically, and the relative excitability of large and small diameter neurons can be manipulated. The factors that play a key role in cuff electrode selectivity are the fact that the target tissues are bundled as a group with a known orientation to the cuff, and the fact that the cuff is usually constructed of an insulating material, which acts to constrain current flow.

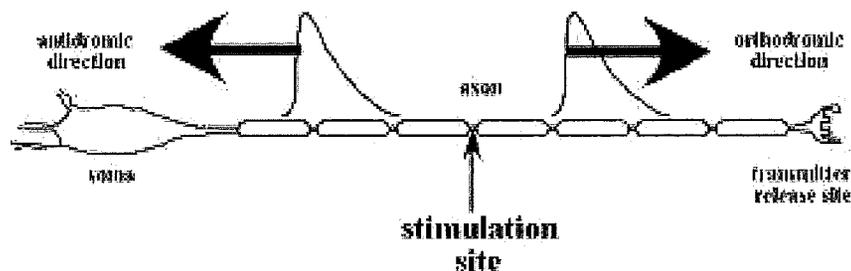


Fig. 12. When a suprathreshold stimulus is applied to an axon, action potentials are created that propagate in both the antidromic and orthodromic directions, starting from site of stimulation.

5.1.4.2 Unidirectional propagating action potentials

Action potentials propagating in only one direction from the site of initiation can be generated by arresting the stimulus initiated action potential that is propagating in the other direction. Depolarization of an axon, in the middle portion of its length, gives rise to two action potentials traveling in opposite directions from the site of initiation (Fig. 12). The orthodromically propagating action potential will result in the release of neurotransmitters from the presynaptic terminal and the antidromically propagating action potential will propagate in the opposite direction. It is generally assumed that the antidromically propagating pulse will have no effect on the cell or receptor end; this may or may not be the case. Unidirectionally propagating pulses can be useful in blocking unwanted neural activity⁷⁴ or creating afferent neural activity without generating efferent activity or conversely creating efferent activity without causing afferent activity.

Van den Honert⁷⁴ described a technique to effect unidirectionally propagating action potentials. The technique involved stimulating the axon to create two propagating action potentials, moving in opposite directions, and then arresting the one propagating in the unwanted direction. In principle, the two propagating action potentials were created at the cathode and the unwanted action potential arrested at the anode, both contacts inside the same cuff electrode.

To arrest a propagating action potential the anodic currents from the electrode must be sufficient to counter the depolarizing action potentials of the invading action potential. The depolarizing currents from the invading action potential are greater than required to reach threshold depolarization and persist for approximately 300 μ s. Therefore, the anodic current supplied by the stimulator must be sufficient to counter these depolarizing currents. However, currents of the required magnitude can be sufficient to create axon excitation at virtual cathode sites, illustrated in the upper panel of Fig. 13.

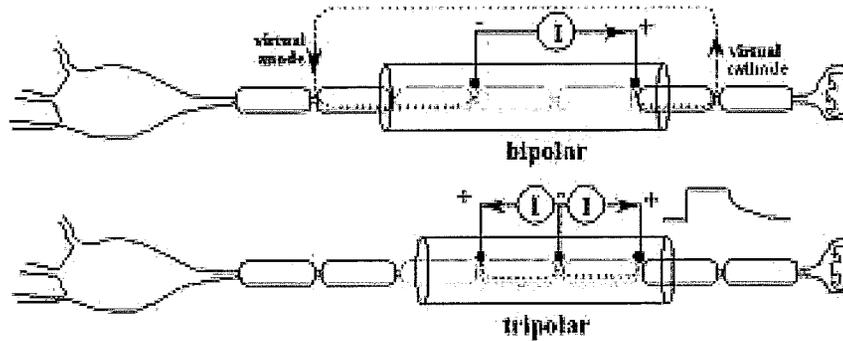


Fig. 13. Stimulation currents entering the axon at the anode can arrest the depolarizing currents of an invading action potential, but in a bipolar configuration currents can exit at a virtual cathode site and initiate a propagated action potential. The propagated action potential created at the virtual cathode site negates the arrested action potential at the anode. The external pathway for current to create a virtual cathode can be eliminated by adding a guard anode, to create a tripolar electrode configuration, at the opposite end of the cuff electrode, as illustrated in the lower panel.

The original technique required an asymmetric tripolar cuff electrode with three contacts, anodes at each end and a cathode placed closer to the arresting anode and further from the escape end of the cuff. To arrest a propagating action potential, a hyperpolarizing, anodic stimulus was applied to nodes at the same time an invading action potential is arriving at that node. For an activating cathode and an arresting anode spaced closely together, the activating stimulus and the arresting pulse could be the same pulse originating from the same stimulator. This assumes that the average delay per node is in the range of 15 to 20 μs . The effect of the hyperpolarizing pulse is to counter the depolarizing effect of the invading action potential and thus arrest further propagation. The depolarizing currents arising from a preceding depolarized node act on the adjacent node for 300–400 μs . Therefore, the hyperpolarizing pulse must be of a similar duration and amplitude. The net effect is that the arrest pulse waveform must have a pulse duration of $\sim 350 \mu\text{s}$ and the amplitude must be greater than what would be required to create an action potential.

Subjecting a nerve to this type of arrest pulse has three effects. At the cathode the stimulus is well above that required to activate many if not all of the smallest fibers. At the anode, the long duration anodic pulse can result in “anodic break” excitation and/or virtual cathode excitation by depolarizing currents arising at the edge of the cuff, close to the anode contact. The “anodic break” excitation can be avoided by using an exponentially decaying lagging edge on the anodic, arrest, stimulus⁷⁵. The resulting stimulus waveform is called a quasitrapezoidal pulse (Fig. 14).



Fig. 14. Quasitrapezoidal waveform required to effect arrest of an invading action potential. The plateau phase is typically 350 to 400 μ s in duration and the time constant of the exponentially falling lagging edge is 500 μ s.

The virtual cathode was suppressed by placing a second anode at the escape end of the cuff to discourage flow of current outside the cuff. In this three-electrode configuration two stimulators were required; the two cathodes were connected to the middle contact, the cathodic current into the electrode contact was the sum of the currents from the two stimulators and the anodic current to the anode at the escape end of the cuff was less than that applied to the arrest anode. The current to the arrest anode was adjusted to yield arrest of the action potential generated at the cathode. The current to the escape anode was adjusted to just suppress the virtual cathode current arising from current flowing outside the cuff from the arrest anode to the cathode, but not to a level where the incoming action potential was arrested. The separation between the middle cathode and the arrest anode is smaller than the separation between the middle cathode and the escape anode. The need for two stimulators was viewed as a complicating factor to this design.

Unger⁷³ reported on a monopolar cuff configuration that was a significant simplification of the tripolar design of van den Honert. Unger used a single stimulator with the cathodic terminal connected to a ring contact inside the cuff and the stimulator anode was positioned in the interstitial space some distance from the cuff. The contact was placed 5 mm from the arrest end of the cuff and the overall length of the cuff was 40 mm (Fig. 15). The Unger design takes advantage of the two virtual anodes created at the ends of the cuff to create the arrest anode and to reduce the likelihood of action potential arrest at the escape anode. The 35 mm cuff length between the cathode and the escape end of the cuff creates resistance inside the cuff to make anodic current flow in that direction less than that toward the arrest end, which allows an escape window. The required 40 mm overall length of the cuff is viewed as a drawback for some applications.

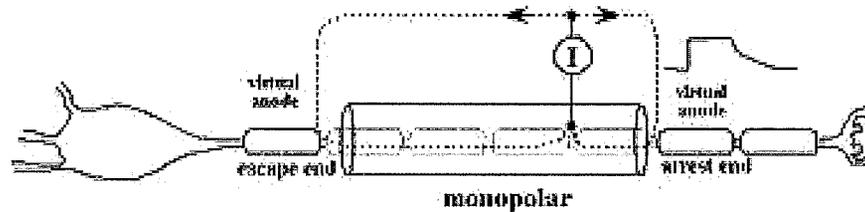


Fig. 15. Schematic drawing of a monopolar cuff configuration developed to effect unidirectionally propagating action potentials. The design utilizes the virtual anode as the arrest site and has no virtual cathodes. In this arrangement, unidirectionally propagating action potentials would be moving in the antidromic direction, toward the cell body.

Sweeney⁶⁸ described a bipolar electrode configuration that could produce unidirectionally propagating action potentials and that had a length that was less than half of the Ungar design (Fig. 16). Lifting the contact at the arresting anode away from the nerve reduced the virtual cathode effect stemming from the current flowing from the arrest anode around the outside of the cuff back into the escape end of the cuff.

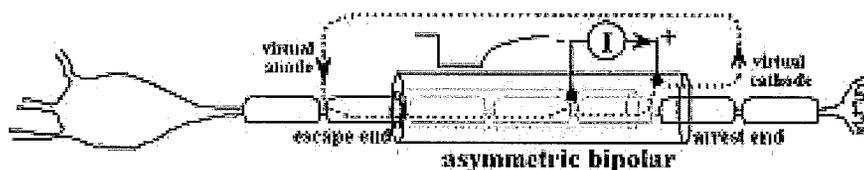


Fig. 16. Schematic drawing of a bipolar cuff configuration that was developed to effect unidirectionally propagating action potentials traveling in the antidromic direction. Elevating the arrest anode away from the nerve suppresses the virtual cathode effect at the arrest end of the cuff.

5.1.4.3. Selective activation of large and small diameter axons

The capacity to selectively and controllably activate axons of different diameters in a trunk carrying mixed populations can enhance the performance of a neural prosthesis. This facility makes it possible to target a specific population and to avoid activation of other populations that may cause undesirable side effects. For example, consider electrically activating a motor nerve having axons that serve both large and small motor units. Recall that large diameter axons preferentially innervate large motor units. These motor units characteristically supply muscle fibers that have poor fatigue characteristics, whereas small motor units usually contain fatigue resistant muscle fibers (see Chap. 1.5). When conventional stimuli, pulse widths of $100 \mu\text{s} \pm 50 \mu\text{s}$, are applied to the motor nerve, the resulting muscle force will be dominated by the force and fatigue characteristics of the easily fatigable population. Similarly, for some applications it may be desirable to preferentially activate large diameter fibers. In this section, our focus will be on ways to enhance the possibility of exciting a particular population of large or small diameter axons.

Noticing that the effect of an applied electric field was greater on large diameter axons than on the smaller diameter axons, Fang²⁵ surmised that the technique developed to arrest action potential propagation would arrest propagating action potentials in the larger diameter fibers at lower stimulus amplitudes than would be required to arrest a propagating action potential in smaller diameter axons when both large and small diameter axons were present in the same nerve trunk. The task was to then show that an action potential traveling on a large diameter axon would be arrested before an action potential traveling on a small diameter axon, thus creating the illusion that the small

diameter fiber would be recruited without activating the large diameter axons. A symmetric tripolar stimulating electrode was employed which would effect arrest at both ends of the cuff. Simulations predicted that larger diameter axons were blocked at lower current levels than smaller diameter axons (Fig. 17).

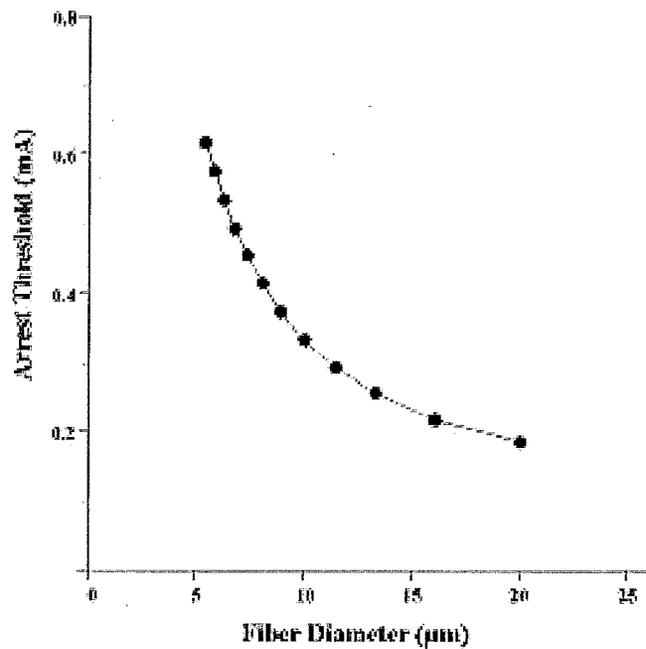


Fig. 17 Arrest threshold as a function of fiber diameter predicted by a analog model analysis (Fang and Mortimer 1991b).

These predictions were confirmed in animal experiments where evoked action potentials were recorded in ventral roots from an electrode placed on the medial gastrocnemius nerve of cat. The gastrocnemius nerve carries both large diameter α motor axons and small diameter γ axons. The larger diameter fibers have a faster conduction velocity, measured as a shorter latency as compared to longer latency for small diameter axons. With narrow rectangular pulse stimulation the largest motor axons were recruited at the lowest stimulus threshold and when the stimulus amplitude was increased to a level that would activate the smallest diameter axon, the larger was also activated. These results are shown in Fig. 18.

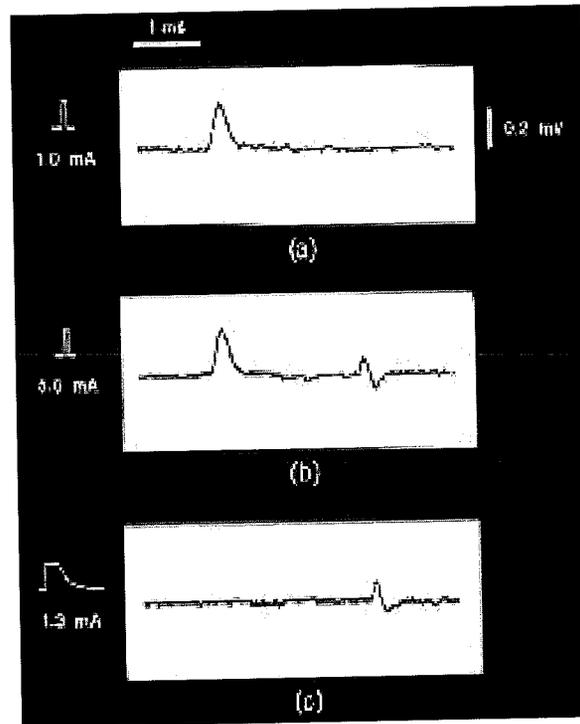


Fig. 18. Single fiber action potentials recorded from a ventral root filament containing one active alpha fiber (120 m/s) and one gamma fiber (40 m/s). Conventional narrow pulse stimuli were applied in the experiments for the results shown in the top two panels, showing that at amplitudes sufficient to activate the small diameter axon the large diameter fiber was recruited at a lower stimulus amplitude. In the lower panel, a 350 μ s quasitrapezoidal was applied at an amplitude that was sufficient to arrest propagation in the large α motor neuron but not sufficient to arrest propagation in the small γ motor neuron. The same result was demonstrated for α motor neurons of slightly different diameters (Fang and Mortimer 1991b).

Fang²⁴ employed the selective arrest technique to demonstrate that small diameter motor axons, innervating fatigue resistant muscle fibers, could be selectively activated without activating large diameter motor axon innervating the large motor units, which are made up of muscle fibers that fatigue in a few tens of seconds. In another report, Fang²³ reported on an experiment where large diameter motor axons were preferentially activated with every other stimulus pulse, by stimulating with a 10 μ s wide pulse and the alternate stimulus pulse preferentially activated small diameter motor axons using a 350 μ s quasitrapezoidal stimulus. The net effect was to create a two motor unit muscle, activating each motor unit separately and alternatively.

Grill and Mortimer²⁷ described a way to manipulate the excitability of large and small diameter axons closer to and further away from the stimulating electrode by using a "pre-pulse". A "pre-pulse" is a subthreshold stimulus with a duration that is usually

several hundred microseconds in duration and precedes the depolarizing stimulus pulse. The technique takes advantage of the fact that the effects of an electrical stimulus are greatest on large diameter nerve fibers and nerve fibers that are closest to the stimulating electrode. These facts apply to hyperpolarizing stimuli as well as depolarizing stimuli.

The effect of the "pre-pulse" is directed at the so-called "h" parameter, which describes the proportion of the voltage gated sodium ion channels in the inactive-activatable state (see Chap. 2.1). Under resting conditions roughly 40% of the sodium ion channels are in the inactivated-inactivatable state ("h" \sim 0.6). A subthreshold depolarizing pre-pulse will increase the relative number of voltage gated sodium ion channels in the inactivated-inactivatable state, making the patch of nerve membrane that experiences the field created by the pre-pulse less easily excitable or raises the magnitude of the stimulus required to initiate an action potential. A subthreshold hyperpolarizing pre-pulse has the opposite effect, e.g., it increases the relative number of voltage gated sodium ion channels that are inactivated-activatable state, ("h" $>$ 0.6), making the patch of nerve more easily excitable.

The results of pre-pulse simulation experiments are shown in Fig. 19. In panel A, when a 500 μ s cathodic pulse was delivered; the 20 μ m axon required a lower stimulus amplitude to initiate a propagated action potential, increasing with increased electrode-nerve separation, and the threshold current was least for the large diameter axon. In panel B, a 500 μ s depolarizing pre-pulse increased the activation threshold for axons closer to the electrode more than for those spaced further from the electrode, meaning that fibers further away from the electrode had a lower threshold than did fibers closer to the stimulating contact, indicated by the region highlighted in yellow. Panel C shows the results when a two step subthreshold pre-pulse was applied.

Two effects stand out. First, the region where distant axons have a lower threshold than closer axon is extended from that shown with the single step pre-pulse (region highlighted in yellow). Second, the small diameter fibers have a lower threshold as compared to the threshold for the larger diameter fibers (stippled region). These results are accounted for by the fact that the inactivating effects of the depolarizing pre-pulse are greater on larger diameter fibers than on small fibers and are greater on axons closer to the electrode than on those more distant.

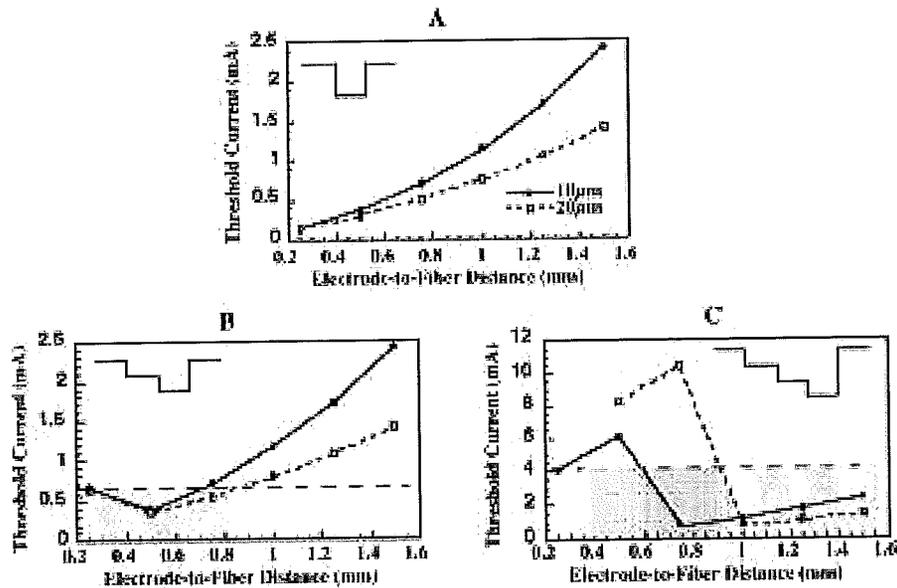


Figure 19. Graphs depicting the threshold stimulus current required to cause a propagating action potential in nerve fibers of two different diameters as a function of separation between the axon and stimulating electrode. These data were collected using a simulation paradigm similar to that described by McNeal (McNeal 1976). The duration of each phase of the stimulus pulse was 500 μ s. Panel A is a graph of the results for a single depolarizing pulse. Panel B is a graph of the results when a single depolarizing pre-pulse was applied. In the yellow highlighted region the fiber more distant to the electrode had a lower threshold compared to fibers close to the electrode. Panel C is a graph of the results when a two step depolarizing pre-pulse was applied. In the yellow highlighted regions fibers further from the electrode had a lower threshold that fibers closer to the electrode. In the stippled region, small diameter fiber had a lower threshold than did the larger diameter fibers (Grill and Mortimer 1995).

5.1.4.4. Selective activation of axons in peripheral nerve fascicles

Axons in specific fascicles of a peripheral nerve can be selectively activated, particularly if the stimulating contact is in close proximity to the fascicle containing the target axons. McNeal and Bowman⁴² hand-placed stimulating electrodes over the target fascicles to achieve selective activation. Under implant conditions it is not possible to align a stimulating contact with each particular fascicle in a nerve bundle. Therefore, under implant conditions it would be desirable to be able to “tune” the electrode by “steering” the applied fields to create a virtual excitation site at or in the target fascicle. Chintalacheruvu,^{17, 18} studied the effects of the simultaneous application of currents to more than one contact in a model of a peripheral nerve with a close fitting cuff electrode

and the electrodes aligned along the long axis of the axons. The simulation results showed that:

- Steering currents applied from contacts placed on opposing sides of the nerve or from contacts that were adjacent to each other on the outside surface of the nerve could alter the region of the nerve where extracellular potentials were at or above threshold. "Field steering" improved the selectivity.
- Longitudinal tripolar configurations were more selective than monopolar configurations. A longitudinal tripolar configuration utilizes three in-line contacts, aligned with the long axis of the nerve, with the center contact providing depolarizing or hyperpolarizing currents and the flanking electrodes acting as the return electrodes. A monopolar configuration has no flanking electrodes and uses a remote return electrode.
- Threshold currents for excitation were greater for tripolar configurations than for monopolar configurations.
- Snug fitting cuffs were more selective than loose fitting cuffs.

A major consideration for the tripolar electrode is manufacturing the electrode/lead assembly. Designs currently in use employ four radially placed contacts, one for a monopolar and three for the tripolar configuration. Four radially placed monopolar electrodes requires four independent leads while four radial placed tripolar electrodes will require at least eight or twelve independent leads.

A lead assembly containing eight or twelve independent conductors, disregarding a connector with this number of conductors, is difficult to construct and is much less compliant than a four conductor lead. This concern provided an impetus for Tarler⁶⁹ to explore the consequences of using a monopolar cuff configuration rather than a tripolar configuration. Experiments were carried out on cat sciatic nerve, which is approximately 3 mm in diameter and contains four major motor fascicles, to quantify the selectivity that was achievable with self-sizing spiral cuff electrodes containing four monopolar and four tripolar radially placed contacts. The results of these experiments showed that ankle torque, in three dimensions and over a range from threshold to full motor axon recruitment, elicited with monopolar and tripolar electrodes was statistically indistinguishable. Therefore, even if a tripolar configuration is the "gold standard", monopolar configurations in a self-sizing spiral cuff, to a first approximation, can be expected to work reasonably well

5.1.4.5. Tunable electrodes

When multicontact cuff electrodes are placed around a peripheral nerve, contacts may not necessarily be aligned with a target fascicle. A remedy could be either to add more

contacts to the electrode assembly or develop a means to "tune" the electrode. With multiple contacts available, virtual excitation sites can be created by superimposing the electric fields generated by simultaneous application of currents to two or more contacts in the electrode assembly.

Tarler has explored "field steering" as a technique to creating virtual excitation sites that are different from the physical location of an actual stimulating contact⁶⁹. These experiments were carried out with self-sizing spiral cuff electrodes, containing four radial contacts, implanted on cat sciatic nerve. The cat sciatic nerve is ~3mm in diameter and contains four major motor fascicles. Tarler found that, by random chance, about two-thirds of the time one of the four contacts was positioned to excite selectively and controllably one of the four motor fascicles in the sciatic nerve. In one of the nine animals, all four contacts could selectively and controllably activate a single fascicle. In those cases where a single contact could not activate a target fascicle, field steering was shown to be an effective means of creating a virtual excitation site confined to a target fascicle. Figure 20 shows the results of an experiment performed by Tarler where "field steering" was demonstrated⁶⁹.

In the experiments shown in Fig. 20, three of the four motor fascicles could be selectively activated, MG, LG and Tib, by contacts 90°, 180° and 0°, respectively. Contact 270° resulted in coactivation of Tib and CP. Selective activation was assured by comparing the torque resulting from stimulation applied to the isolated nerve branch to the CP, MG, LG, and Tib, with the torque recorded when stimuli were applied to each electrode contact. When an anodic stimulus was applied to contact 0°, while a cathodic stimulus was applied to contact 270°, a virtual excitation site was created for the CP fascicle.

Two additional observations can be made from the results depicted in Fig. 20. First, if an electrode contact is reasonably close to a fascicle, it appears to be fairly easy to isolate the stimulus to that fascicle. Under these conditions, which have occurred quite often over the last decade in our laboratory, it is possible to recruit all of the motor fibers from threshold to full recruitment before axons in adjacent fascicles were activated. Second, when looking at the recruitment characteristics of the tibial nerve, there is a hint that subfascicle selectivity may be possible. The tibial nerve serves several muscles that operate around the ankle joint, with two groups dominating the torque profile. The two groups form the sides of a parallelogram (shaded in Fig. 20). When stimulus currents are applied to contact 0°, the group producing predominately medial rotation is activated first followed, at higher stimulus levels, by the component producing more plantar flexion. On the other hand, when stimuli are applied to the contact on the tibial branch, the order in which the fascicles are recruited is reversed. There is a strong indication here that motor axons serving a specific muscle are collected together rather than being randomly placed in the fascicle.

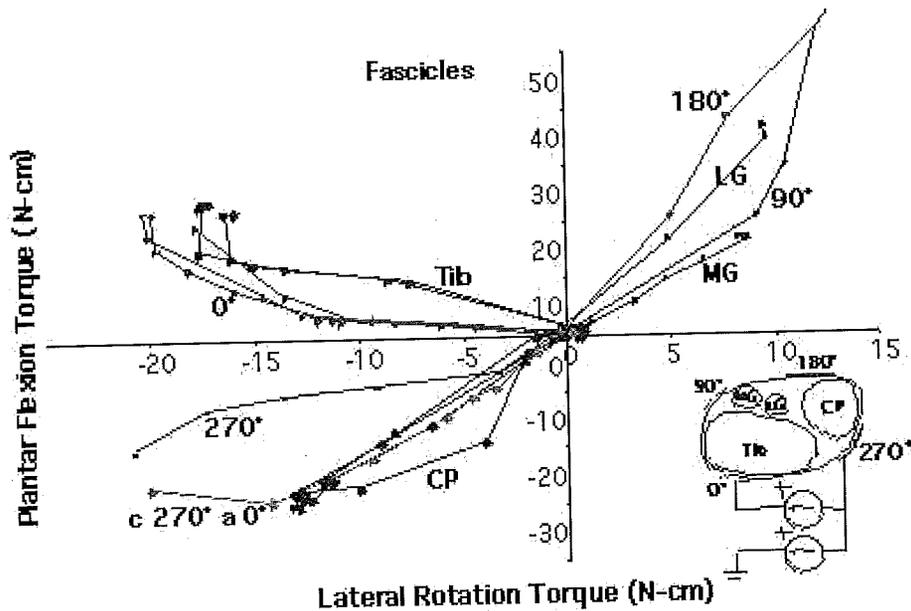


Fig. 20. Data reported by Tarler showing that “field steering” techniques can be used to create virtual excitation sites or tunable electrodes. The coordinates of the plot are ankle torque in two dimensions, Planter Flexion/Dorsi-Flexion and Medial/Lateral Rotation. Data shown are for evoked ankle torque resulting from stimulation applied to various contacts within the self-sizing spiral cuff electrode. Also included on this graph are torque measurements recorded when stimuli were applied to each of the four isolated motor nerves, labeled Tib, CP, MG and LG. The drawing, shown in the lower right hand portion of the figure, provides an approximation for the nerve anatomy relative to the position of the four electrode contacts labeled 0°, 90°, 180° and 270°. A schematic of the stimulator configuration used to apply current for the multiple contact electrode is also shown. Single dots represent data collected at different stimulus levels. In this experiment, the Mg, the LG and the Tib branches were selectively activated over the full range by contacts 90°, 180° and 0° respectively. Stimuli applied to the 270° contact appeared to activate both the tibial and common peroneal fascicles. Anodic steering (designated c270°a0°), anodic current applied to contact 0° made it possible to activate selectively only the CP fascicle from the self-sizing spiral cuff electrode {NB: this doesn't correspond to what is on the figure} (Tarler 2000).

5.4.1.6. “Simultaneous” activation of more than one target group of axons

Consider the challenge of producing a motor response that is the sum of torques produced by simultaneous electrical activation of two motor axon populations, each serving a different muscle acting around a common joint. If the stimulating contacts are sufficiently far apart, the stimulation induced fields do not interact. However, if the contacts are sufficiently close together, the induced electric fields can overlap to effect

depolarization of a larger number of axons than the sum of the axons activated when stimuli are applied separately.

For example, when axons in fascicle Tib are activated by a cathodic stimulus applied to contacts 180° and an anodic stimulus applied to 90° ((c180°a90°), Fig. 21), a torque is measured as shown in Fig. 22. Similarly, when a stimulus is applied to contact 0° Torque (c0°) torque is measured,.

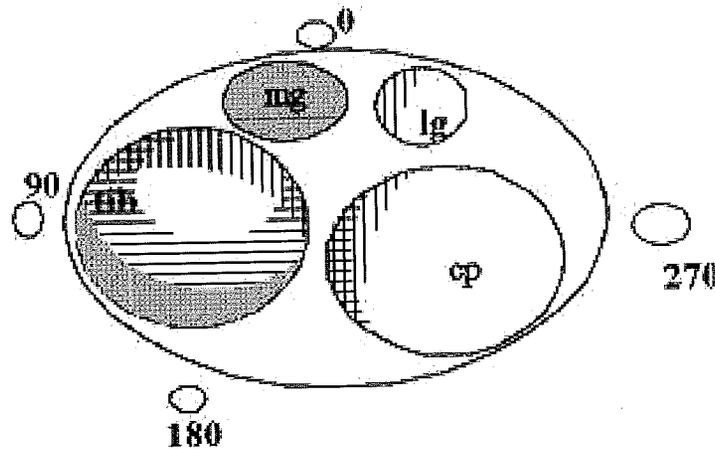


Fig. 21. Schematic representation of cat sciatic nerve containing four motor fascicles, tibial (tib), medial gastrocnemius (mg), lateral gastrocnemius (lg) and common peroneal (cp). Electrode contacts in the self-sizing spiral cuff electrode are labeled 0°, 90°, 180°, and 270°. Grayed areas represent axon populations activated when stimuli (c180°a90°) and (c0°) are separately applied. The vertically hatched areas depict axons stimulated to subthreshold levels by (c0°), and horizontal hatched areas depict axons stimulated to subthreshold levels by stimuli (c180°a90°). Regions where the two subthreshold regions overlap to create suprathreshold excitation have overlapping horizontal and vertical hatched areas.

The grayed area in Figure 21 depicts the axons that are depolarized by the stimulus when stimuli are applied to activate only one of the two populations of axons. The vertical hatched area depicts axons that have been partially depolarized by stimuli applied to the 0° contact and remain hyperexcitable for a period of time following the application of the stimulus. The horizontal hatched region represents the axons that have been partially depolarized by stimuli applied to contacts 90° and 180° and remain hyperexcitable for a period of time following the application of the stimulus.

When stimuli are applied at the same time to contacts 0°, 90° and 180°, the hyperexcitable regions overlap and the torque produced by these axons is added to that produced by the axons in the grayed regions. Under these circumstances the resulting torque is not a linear sum of the torques produced by axons in the grayed regions. A linear sum of the two torques would be a torque in the area of the upper right hand portion of the graph shown in Fig. 22 (circle labeled "Expected torque sum"). Instead of

the torque that was desired, a torque in the left hand portion of Fig. 22 was recorded (circle labeled "Combined stimulation with 20 μ s delay").

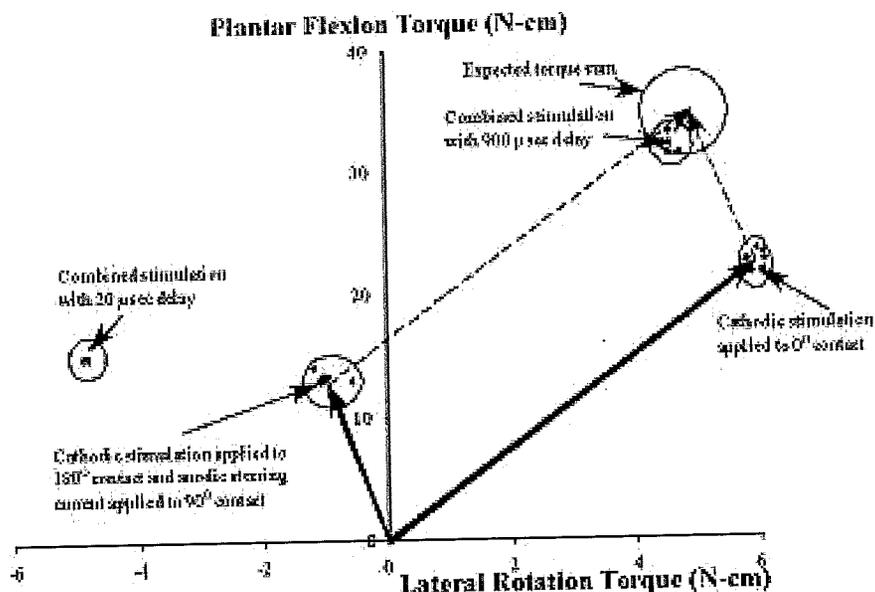


Fig. 22. Graph of torque measured when stimuli were applied to effect activation of two separate populations of motor axons. The bold lines represent the torque measured when separate stimuli were applied. When the stimuli were applied with a separation of 20 μ s, which is essentially with no delay between the stimuli, the resulting torque was that shown circled in the left hand portion of the graph. When the stimuli were applied with a 900 μ s separation between the pulses, the resulting torque was a linear addition of the separately evoked torques (Tarler 2000).

Excitation of axons in the subthreshold-hyperexcitable regions can be avoided if a delay is introduced between the time a stimulus is applied to effect activation of one set of axons (e.g. grayed area in the tibial fascicle and the other set of axons, the grayed population in the medial gastrocnemius fascicle). The delay must be sufficiently long to allow the axon membranes to recover from a hyperexcitable state and sufficiently short to avoid a physical response that appears as two separate responses, i.e., contractions. Tarler found that a delay of 700 to 900 μ s was long enough to enable full recovery from the hyperexcitable state and still be within the refractory period of all axons⁶⁹. Stimuli applied to two motor nerves separated by 700 to 900 μ s appears at the joint as if the stimuli were applied simultaneously. Experimentally, when a 900 μ s delay was added between the stimuli to the two populations, Tarler recorded a torque that was a linear addition of the torque vectors when stimuli were applied separately (upper right hand portion of Fig. 22).

5.2. Intra-neural electrodes

Many of the neuronal structures targeted for stimulation are embedded in surrounding neural tissue, particularly in the central nervous system. To gain electrical access to these structures without excitation of intervening cells gave impetus to the exploration of electrodes that penetrate into the neural tissue. There is a trade-off between specificity of stimulation with lower current usage on one hand and some damage to the penetrated tissue on the other. This approach has also been applied to peripheral nerves, to closely approach a nerve fiber for stimulation or recording. It was thought that to selectively stimulate any particular nerve fiber, an electrode had to be applied close to the fiber inside the nerve. Intra-neural electrodes are positioned to penetrate the epineurium around the nerve trunks. Subsets of these electrodes are meant to enter the perineurium around the fascicles and go between the nerve fibers and are called intrafascicular electrodes. Intra-neural electrodes, which do not enter the fascicles, have also been termed *inter-fascicular* electrodes.

An early method used coiled wire electrodes inserted into the nerve¹⁰ Electrodes were implanted in rabbit tibial nerve and no significant changes in nerve conduction velocities were observed up to 9 weeks post-implantation. There was little change in motor current threshold beyond 10 days post-implantation. The nerves were reported to show little histologic demyelination or denervation in most specimens. Platinum and Platinum-Iridium, bipolar wire electrodes have been implanted intra-neurally in experimental animals for recording nerve activity^{35, 38, 47}.

Veltink et al. published a modeling study of nerve fascicle stimulation of small monofascicular rat common peroneal nerve and multifascicular human deep peroneal nerve⁷⁷. They also used intrafascicular and extraneural electrodes on rat common peroneal nerve. They reported that recruitment was more stable for intrafascicular electrodes than for extraneural electrodes with a lesser overlap of recruited motor unit groups with intrafascicular than for extraneural electrodes⁷⁶.

Pairs of Pt-Ir intrafascicular wire electrodes have been implanted in cats to determine if these could selectively activate separate subsets of axons in a single fascicle. An average overlap of activated nerve fibers was reported to be 5.5% between fascicles and 27% within a fascicle⁸¹. They also found a reduction in fatigue with the intrafascicular electrodes in cat gastrocnemius muscle; using interleaved dual channel stimulation⁸⁰.

Micro-machined electrodes exploited the feasibility of multiple electrodes in the dimensions suitable for approaching nerve axons. These electrodes were first fabricated with three or four shanks, each with active sites with area between 400 to 1600 μm^2 ⁷⁹. Electrodes were subsequently developed with greater numbers of active sites. It was thought that the electrodes should lie on a grid with a distance between electrodes based on the distances between the nodes of Ranvier. A linear 12-electrode array was used to

study selectivity of stimulation in the peroneal nerve of the rat ⁵⁸. Selectivity was found to be highest when two electrode sites were separated by 200–250 μm ⁵⁹.

An intraneural electrode was developed to slowly penetrate the fascicle in order to lower the trauma of acute insertion. This slowly penetrating interfascicular nerve electrode (SPINE) was reported to penetrate the nerve within twenty-four hours without evidence of edema or damage to the perineurium and were showed functional selectivity in majority of experimental trials ⁷².

A silicon-based array of microelectrodes, which contained 25 to 100 electrodes, was used on the cat sciatic nerve, using a high velocity insertion technique. Currents at 10 μA range evoked muscle twitches and were stable for up to 60 h. ¹².

Since the mid 90's, research and development in micromachined stimulating electrodes and microelectrode arrays have been carried out under the 'Neural Prostheses Program' funded by the National Institute of Neurological Disorders and Stroke, National Institutes of Health. The results of these and other electrode development projects have been detailed in the progress reports by the individual research teams (see Reference).

6. Summary

Muscles can be activated by electrodes placed on the surface of the skin, on the surface of the muscle, in the muscle, on the motor nerve or in the motor nerve. Each position of the electrode carries different attributes that should be taken into account when designing a motor prosthesis. Electrodes placed on the surface of the skin require the largest relative stimulus amplitude to activate muscle and result in a diffuse stimulus field that may give rise to unwanted movements and/or sensations. Placing stimulating electrodes closer to the target tissues by implanting them under the skin reduces the stimulus magnitude required to activate the nerve fibers and improves the likelihood that the stimulus will not cause activation of non-target neural tissue.

The effect of an applied electric stimulus is greater on large diameter axons than on small diameter axons and greater on axons that are closer to the electrode than on axons that are farther from the electrode. This means that if a stimulus is applied to effect axon depolarization, the larger axons close to the electrode will be activated at the lowest stimulus currents. Similarly, if a stimulus is applied to effect axon hyperpolarization, the larger, closer axons will be the most affected at the lowest stimulus currents. This finding opens opportunities to activate select neuron populations.

In skeletal muscle, as opposed to cardiac muscle, muscle cells are activated either directly by the applied stimulus or through their nerve supply rather than by propagation from adjacent muscle cells. Therefore, for direct muscle activation the stimulus level must be sufficient to activate all muscles cells of interest, which is usually all of the muscle cells in the muscle. Because the electric potential that results from an applied stimulus decreases inversely to the separation between the electrode and target cell, very

large stimulus amplitudes are required to directly activate muscle cells only a few millimeters away from the electrode. These amplitudes can easily be in excess of values considered to be noninjurious for all but the smallest muscles. For this reason, motor prostheses are considered practical only for muscles that retain their motor innervations.

Intramuscular electrodes are relatively easy to implant, particularly those having a percutaneous lead. They can be inserted with a hypodermic needle. The coiled wire intramuscular electrode is tolerated well by body tissues, in the subcutaneous tissues and at the sites where the electrode exits the skin, when the electrode is used as a percutaneous electrode. The compact cell layer formed around implanted devices provides a barrier that suppresses bacterial entry into the tissue spaces and a barrier to nutrients required to sustain bacterial growth in the area occupied by the wound lead. The "open" helix and the loose connective layer permit the lead to extend and compress under axial loads without a piston like action as would occur with a closed cylinder lead under similar loads. Piston like actions are believed to induce cell trauma and hence a chronic inflammatory response.

Cuff type electrodes can be used to effect a degree of selective activation, selectivity, that is not achievable with other configurations. Specifically, action potentials can be created that propagate in only one direction from the site of their initiation, antidromically or orthodromically, and the relative excitability of large and small diameter neurons can be manipulated. The factors that play a key role in cuff electrode selectivity are that the target tissues are bundled as a group with a known orientation to the cuff and that the cuff is usually constructed of an insulating material, which acts to constrain current flow.

Axons in specific fascicles of a peripheral nerve can be selectively activated, particularly if the stimulating contact is in close proximity to the fascicle containing the target axons. When multicontact cuff electrodes are placed around a peripheral nerve, contacts may not necessarily be aligned with a target fascicle. The simultaneous application of stimuli from more than one contact, "field steering", creates excitatory fields that are positioned at sites different than the individual electrode contact, "virtual electrodes."

The most recent technology to come on the scene involves electrodes inserted into the peripheral nerve. These contacts are in close proximity to many of the target fibers, which means that the stimulus threshold would be lowest of all the electrode configurations presented in this chapter.

7. Addendum: Electrode Cleaning Instructions

7.1. Objective

The cleaning process is carried out on components and fabricated parts and devices to ensure a product that is maximally free of extraneous surface contaminants.

7.2. Consumables

Ultra pure water (Resistivity ~18Mohms-cm)

Freon TMS-167 (Freon may not be available and a suitable substitute would need to be found)

Safezone TMS-197 (Miller-Stephenson, Morton Grove, IL 60053, www.miller-stephenson.com)

Ethanol

Liquinox detergent (Alconox, Inc., White Plains, NY 10603, www.alconox.com)

Clean gloves.

7.3. Equipment

Ultrasound bath

Clean glass container for storing electrodes

7.4. Preparation

1. Prepare liquinox detergent solution by mixing with ultrapure water in the ratio of Liquinox: UPW = 1:10.
2. Check to ensure that there is sufficient water in the ultrasound bath to partially immerse the container used, without overflow onto the devices.
3. Place items to be cleaned in glass container.

7.5. Precautions

Silicone containing products are NOT to be cleaned in either Freon or Safezone (both are used as degreasers) because these chemicals can cause mechanical distortion of devices using silicone rubber. Start process at Step 3 (below) for those products containing silicone rubber. Do not touch cleaned items without wearing clean gloves that are free of particulate matter (e.g., talc).

7.6. Procedure

1. Sonicate in Freon (TMS-167) for 5 minutes.
2. Sonicate in Safezone (TMS-197) for 5 minutes.
3. Sonicate in prepared Liquinox/UPW mixture for 5 minutes.
4. Pour out solution and rinse in ultra-pure water.
5. Sonicate in ultra-pure water for 5 minutes.
6. Sonicate in ethanol for 5 minutes.
7. Sonicate in ultra-pure water for 5 minutes
8. Remove from bath and allow to dry on clean surface.

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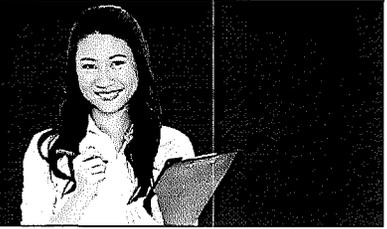
The Consumers' Guide



**Acupuncture and
Oriental Medicine
Practitioners**



The Consumers' Guide



What is Acupuncture and Oriental Medicine?

The practice of Acupuncture and Oriental Medicine (AOM) is an ancient system of medicine that dates back over 3,000 years and is a unique system of techniques that treats illness and improves health by stimulating prescribed points on the body. Acupuncturists assess a patient's syndrome or pattern of disharmony by using a set of diagnostic skills that involve questioning, palpation, visual inspection, and olfactory-auditory data collection. By discriminating the exact pattern of the body's physiological response to pathogenic factors, an acupuncturist determines the necessary treatment strategy to prompt the healing process. These therapeutic interventions include acupuncture, electro-acupuncture, cupping, manual therapies such as acupressure, moxibustion, and exercises such as tai chi or Qi gong, as well as Chinese herbal preparations and dietary therapy.



What Are the Benefits of Acupuncture and Oriental Medicine?

Although many patients see acupuncturist for pain management there are many conditions that are alleviated by acupuncture and Oriental medicine therapies including but not limited to the following:

Allergies & Asthma	Anemia
Anorexia	Anxiety
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Cold & Flu	Colitis/ Crohns
Constipation	Depression
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Emphysema	Endometriosis
Food Allergies	Gastritis
Headaches & Migraines	Hypertension
Hypoglycemia	Incontinence
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Irritable Bowel Syndrome	Muscle Spasms
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Ulcers	

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OUTLINE OF THE HISTORY OF ACUPUNCTURE IN EUROPE

By Elisabeth Hsu

INTRODUCTION

This presentation is mainly based on secondary sources of the history of acupuncture.* It will be divided into two sections. The first will report on the practice of so-called "acupuncture" in Europe, and the second on Western inquiries into the principles according to which the Chinese practise acupuncture. The division is artificial because someone who inserts needles into a patient's body does not necessarily practise *acupuncture*. He can only be said to practise *acupuncture* if he inserts the needles according to the principles of *Traditional Chinese Medicine* (TCM). However, in the light of the historical data, the division seems to be necessary.

The knowledge of acupuncture in Europe was generally derived from reports by travelling doctors on the one hand, and treatises by Jesuit missionaries on the other. These writers had different training, knowledge and interests, and they emphasised different aspects of Chinese medicine. In other words, we observe a close correlation between the profession of the writers who wrote on Chinese medicine and the content of their writings.

I shall therefore concentrate on the material which was written by doctors and concerns more the practice of so-called "acupuncture" in Europe in Section One. The treatises which were mainly written by Jesuits and report on the concepts and modes of reasoning in TCM will be presented in Section Two. In the summary I will give a short outline of the historical events and discuss them in the light of the above observations.

* These secondary sources include a short history of acupuncture in Germany by Arnold (1976), a chapter in Lu and Needham (1980) and a book on acupuncture in France during the 19th century (Geoffroy 1986) as well as a few articles and some doctoral theses (Buet 1977, Heise 1985). In addition, information on 20th century developments has been obtained from interviews with a few acupuncture practitioners including the healer who was the first to teach acupuncture in Britain, and the president of the "Association Francaise de l'Acupuncture" (AFA).

PART ONE: THE PRACTICE OF "ACUPUNCTURE" IN EUROPE

17TH CENTURY

The Dutch doctor W. Ten Rhyne is considered to have written the earliest important report on acupuncture. The word "*acupunctura*" was probably coined by him.

His treatise "*Dissertatio de Arthritide; Mantissa Schematica; De Acupunctura; et Orationes Tres*" published in 1683, contained much information on the technique of needling and was later of particular interest to the practitioners of "acupuncture" in Europe.

In the first part of his treatise he discusses the aetiology, the symptoms and the therapy of "*podagra*"*. In the beginning of the second part he declares that the principles of Chinese and Japanese doctors are far too difficult to explain and that he will therefore limit himself to the discussion of two Chinese and two Japanese figures which represent the meridians. He called the lines drawn on the surface of these figures "*vasi*" (veins and arteries), which led to much confusion in later times. In the third part, entitled "*De Acupunctura*", he discusses different types of needles (silver, golden etc.) and different modes of puncturing (eg the needle is inserted by rotation, or it is hammered into the skin with a small hammer). He is aware of the possibility of treating pain by needling a distant acupuncture point. He also understands that needling has an effect on "*Qi*" (which he translates as "*flatus*" or "*Spiritus*"), but he misunderstands its purpose and effect: "... *ut flatus ille avolet*" (in order to let the breath fly away) finally he gives in a single paragraph, medical indications for acupuncture treatment.

*Podagra: gout of the foot or big toe, but possibly having a wider meaning at this time.

Ten Rhyne was a doctor of the Dutch East-India Company, and his report, based on the information he had gathered in his two-year stay in Nagasaki, is one traveller's report among others by doctors of the company. It was preceded by J. De Bondt's (1658) and A. Cleyer's (1682) publications, and followed by a more extensive and detailed report by E. Kaempfer (1712).

Jakob De Bondt mentions Chinese medicine once and says, full of admiration, that what the Japanese do with their "*stylus argenteus*" (acupuncture needle) outstrips miracles (cf. Arnold 1976:25).

Engelbert Kaempfer gives a more comprehensive account of Chinese medicine. In "*Amoenitatum Exoticarum Politico-physicomedicarum Fasciculi Quinque*" (1712), one chapter is devoted to acupuncture, one to moxa, and one contains an annotated illustration of *Kjusju* (= *Zhenjiu* = Acupuncture and Moxibustion). Like Ten Rhyne, he recognises the therapeutic effects of distant puncturing but not the importance of pulse diagnosis, which he hardly mentions. His attitude towards Chinese and Japanese medicine is, like De

Bondt's, most favourable and his enthusiasm is best illustrated by the following metaphors: he speaks of "the inhuman surgery of the Western world" using "cruelly injuring steel", while the Japanese are said to cure "with the mild fire of the royal plant Artemisia" (moxa), or by means of "the noble metal of the fine needle" (acupuncture) (cf. Arnold 1976: 33).

The travelling doctors of the Dutch East-India Company had witnessed how acupuncture was practised and were impressed by its therapeutic effects and techniques. Their contact was with Japan rather than China, since the Netherlands had the right of exclusive trade with Japan from 1641 onwards. They recognised the relatedness of Chinese and Japanese therapies and their treatises contained some information on what is nowadays considered TCM, but they also contained much distorted information.

It is striking that Ten Rhyne gives a very detailed account of static, materialist entities such as the material of the needles (which is not of major concern in TCM). His report has often therefore been characterised as being practice-orientated whereas the principles of TCM which he scarcely discusses, in fact form an important part of the practice of acupuncture.

This interest in static, easily observable entities, has to be seen in the context of European science and medicine during the 17th century - a period of most decisive findings for modern science with a fundamental change of outlook. In medicine, two new fields of investigation were developed: physiology and microscopic anatomy. Marked by an interest in iatro-physics, observations in a more physiologic framework were made in Padua. Microscopic anatomy, on the other hand, was much promoted by A. von Leeuwenhoek (1632-1723). Leyden in the Netherlands eventually became a major centre of research, its influence being at its peak during the time of H. Boerhaave (1688-1738), a successful clinician and medical teacher (Ackerknecht 1982).

Ten Rhyne's Dutch background suggests that explanations in terms of a more physiological outlook - an understanding in terms of functions such as we cultivate nowadays for understanding TCM - were not of primary concern to him. Moreover, why should a 17th century doctor be interested in pursuing aspects of medical research which had similarities with the scholastic medicine of the Middle Ages? Notions such as "elements" (*Wu Xing* = five Phases) or "Spiritus" (*Qi* = Energy, Influence) were exactly what European medicine was seeking to overcome.

18TH CENTURY

Kaempfer's report in 1712 was to be the last one of major importance for more than a century by a traveller who had been to the Far East himself. During the 18th century, particularly in Germany, Chinese medicine was either criticised (eg Stahl 1733) or ignored. This lack of interest in Germany may well be illustrated by the fate of L. Heister's essay "*Vom Nadelstechen der Chineser und Japonenser*". It was printed in his "*Chirurgie*" in 1789, reprinted in a later edition (1763), but did not appear in

The knowledge of acupuncture in Europe was generally derived from reports by travelling doctors on the one hand, and treatises by Jesuit missionaries on the other.

his "*Kleine Chirurgie*" in 1767. Although Heister had a favourable attitude towards Chinese culture, he could not appreciate the Chinese medical system: "...and one wonders how such prudent nations can have such a high opinion of these strange remedies". This characterisation of Chinese medicine was based on the reports of Ten Rhyne and Kaempfer, which seem to have been the standard sources of knowledge for Chinese medicine up to the 19th century. Who would want to blame its many critics?

In France, Chinese medicine was better known. The Jesuit Du Halde, for instance, includes in his "*Descriptions Geographiques, Historique, Chronologique, Politique et Physique de l'Empire de la Chine et de la Tartarie Chinoise*" (1735) detailed descriptions of Chinese medicine: it contains Kaempfer's descriptions of acupuncture, refers to the concept of meridians, and includes

translations of Chinese medical classics about pulse diagnosis and recipes of various pharmacopeias. Dujardin's "*Histoire de la chirurgie depuis son origine jusqu'a nos jours*" (1744) contains information which he extracted from the publications of the doctors of the Dutch East-India Company. Furthermore, the

dissertations which were written on Chinese medicine in France (eg Bridault 1757, Deidie 1787) reflect some interest in Far Eastern medicine.

19TH CENTURY

It was in France that the practice of "acupuncture" was in vogue at the beginning of the 19th century, and from there it spread to other European countries. L.V.J. Berlioz is considered the first to have used acupuncture needles for treating patients and to write reports on his medical successes. From the time of his first publication (in 1816), until about 1825, needling spread among French practitioners, mainly for treating cases of neuralgia and rheumatism. With a delay of about ten years it spread also to England, Germany and Italy. However, this fashion of needling had a short life. No similar reports from the latter half of the 19th century have been found.

The upsurge of acupuncture at the beginning of the last century is puzzling and the question arises as to what factors conditioned its occurrence. In this essay we cannot discuss the question exhaustively. We can only point to some possible conditioning events. For instance, we may remind ourselves that criticism of Chinese medicine seems to have been very severe in Germany during the 18th century, while more sympathetic treatises on Chinese medicine were published in France at a slow but constant pace. Moreover, the revolution had abolished many old institutions, and as a result, innovations in every field of study were facilitated in France. In medicine, the institutionalisation of hospitals gave access to unprecedented material for clinical observation, physical examination and also for autopsies. When reading of Corvisat, Bichat, Laennec, Bretonneau and many more, one is struck by the almost visible growth of knowledge in pathological anatomy. In this atmosphere, doctors were probably interested in experiments, including those involving the treatment of patients with needles.

To explain the rapid decline of needling, one may want to reason that due to the achievements of clinical medicine, needling was soon overcome. However this reasoning does not hold if we look at the development of medical practices in Germany. Although the situation in Germany was quite different at the beginning of the 19th century, we are tempted to point to a parallel practice of a non-orthodox medicine: the rise of homoeopathy. Unlike needling, homoeopathy did not sink into oblivion, even though, during the latter half of the 19th century, it was in Germany that the advances in clinical medicine were the most rapid.

Unlike needling of the early 19th century, homoeopathic therapies were constantly practised according to a theoretical framework. The principles of homoeopathy were put to forward by Samuel Hahnemann (1755-1843). They were based on his findings that same is cured by same (*similia similibus curantur*) and stood in stark contrast to the practices of clinical medicine at that time, so-called allopathic medicine. These principles were to be empirically tested and Hahnemann never stopped to integrate new observations into his theoretical considerations which he published in the repeated revisions of the "Organon" (1810-1833). It seems that, apart from other factors, the different attitude towards a theoretical foundation of the practice conditioned the different development of these two non-orthodox therapies; homoeopathy continued to be practised and researched while needling was totally abandoned in the later part of the 19th century.

Most doctors of the early 19th century applied only the so-called "locus dolendi" mode of treatment (Feucht 1961) where localised pain was treated by the local insertion of needles. This practice was not only wrong according to the principles of TCM, but also brutal. It was for instance common to use a large number of needles and to leave them in the body for hours (cf. the report of an Italian doctor that 38 needles left in the vertebral column for eight hours had cured an epileptic child (Geoffroy 1986:135). In the middle of the century, acupuncture needles were totally estranged from their original purpose: they were described as useful for exploring the contents of tumours and for facilitating the coagulation of blood in the vessels etc. (cf. *Nouveau Dictionnaire de Médecine et de Chirurgie Pratiques 1864*, cit. Geoffroy 1986:148). Sarlandiere (1835) was perhaps the only practitioner who was fully aware of the possibility of treating pain by needling a distant acupuncture point, but he developed an idiosyncratic system of "electro-puncture".

Nobody seemed to feel the need to consult Chinese sources, not even Abel-Remusat the first professor of Sinology in Europe, at the College de France. In 1825 he wrote a valuable short and critical essay "Sur l'Acupuncture". His attitude towards the practice of needling was generally favourable, although he concluded that it was a method which needed to be studied at length before its efficacy could be definitively judged. The kind of study he was referring to was by no means that of Chinese medical classics. He smiled at Sarlandiere for believing that Chinese practitioners had any principles on which to base their practice. Sarlandiere, he said, treated the Chinese with much honour while in fact, they appeared to act haphazardly, "guided by intuitions of an ignorant empiricism" (Abel-Remusat 1829:378).

Only a few individuals of the 19th century advocated the investigation of the sources of Chinese medicine. Kerber (1832), for example, compared Ten Rhyne's and Kampefer's reports with a translation of 110 aphorisms of Chinese medicine (by I. Titsing cf. Section Two), and came to the conclusion that European and Chinese acupuncture were two quite different techniques.

Captain Dabry de Thiersant is another person who made inquiries into the original sources of acupuncture, and was the first to go to China after a long lapse of direct contact. He was not a doctor, but he learned Chinese and he wrote a 579-page study on Chinese medicine: 340 pages concerned the treatment of internal, external, women's and children's diseases, 70 pages explained acupuncture points, point by point, their location and medical indications, and 70 pages described veterinary medicine. He was aware of a circulating "Qi", of the "Jing" (meridians) and his four tables of the acupuncture points are very detailed. But his work was ignored or considered scientifically useless (cf. Hubotter 1929) and it had no impact on research into the theory of Chinese medicine.

20TH CENTURY

The 20th-century interest in acupuncture is closely linked to Georges Soulie de Morant. The story goes that he was very impressed by the achievements of TCM during a cholera epidemic in 1908 when he was Consul in Yunnan-fu (Kunming) and that from then onwards, the French diplomat in China pursued the interests of his youth in medicine. Back in France, encouraged by P. Ferreyrolles, he translated Chinese medical classics and began to teach acupuncture. Unfortunately his translations were interspersed with his own ideas and he taught his students in the terminology of Western medicine with which they were already familiar. His work has led to the flowering of the over thirty acupuncture associations in France, each with its own curriculum and its own idiosyncratic theory.

In the late forties and early fifties R. de la Fuye organised the first acupuncture association in France, the AFA, as well as several international congresses. This led to the foundation of the first acupuncture association in Germany (in 1951/52). From Germany the practice of acupuncture spread to other German speaking countries and in the early sixties to England. This picture is of course oversimplified and one should bear in mind that such individuals as Dr. Felix Mann in England began to practise acupuncture independently of the above streams.

Acupuncture as an alternative to orthodox Western medicine has steadily gained in popularity as the statistics of various acupuncture associations show. However, it seems that practitioners have only recently turned their attention to acupuncture as it is practised in China, and it seems to be more recent still that research into the medical classics has been promoted on a larger scale.

PART TWO: WESTERN INQUIRIES INTO THE CONCEPTS AND MODES OF REASONING IN TCM

Yin Yang, Wu Xing, Qi, Xue are some of the key concepts which are nowadays known in the West, among scholars and practitioners (although even nowadays not necessarily with the same meanings as in China). Recently a large number of articles and books have been published; work of Western medical research and of investigations into TCM "theory" (eg in Europe Hubotter, Bridgman, Needham et. al., Porkert, Schnorrenberger, Unschuld, Despeux etc.). This interest in the systemic thinking of TCM and its historical development, the attempt to understand the logic and science of the Chinese people, seems to be unprecedented in European history. Ma Boying speaks of the "Needham period" which began no earlier than the beginning of this century (ca. 1930). While the present mode of inquiry into the concepts of TCM is a fairly recent development, it is striking that discussion of the terminology and theory of TCM were already recorded in treatises of the 17th century. These few treatises will be discussed in the following.

The earliest known text was written in 1654 by Jean Siu, a Chinese doctor who had been converted to Christianity. In the first part of the text, the dysfunctions of the orbs and the predicted course of the disease are described. The second part contains prescriptions for the treatment of wounds and inner lesions. In one passage, acupuncture points are mentioned and translated as the "108 cavities of the body". This is probably the earliest reference to the acupuncture points in Europe (cf. Buet 1977).

Jean Siu's text remained unpublished for more than two hundred years. Its translation was given to Toye by pere Vernez in 1854 and published in Toye's "Note sur l'Art Medico-chirurgicale Chez les Chinois" in 1864. Similarly, the text "La methode du Cong-Fou ou Cinesologie ou la Science du Mouvement" by pere Amyot (1718-1793) who was one of the last members of the Jesuit mission in Peking, was published well into the 19th century, in Dally's "Cinesologie ou Science du Mouvement" (1857). In the late 18th century Isaac Titsing, a high official of the Dutch East-India Company and thereafter ambassador in China, translated a treatise by a Japanese doctor (cf. Abel-Remusat 1825:374) which consisted of 110 aphorisms, but his translation remained unpublished until Sarlandiere published it in the 19th century.

It is noteworthy that these treatises were all published in the mid 19th century: they had not preceded and prepared the great boom of needling in the 1820's. On the contrary, it seems that the interest in theoretical considerations of Chinese medicine arose due to the widely practised locus dolendi acupuncture.

The first published treatise by a Jesuit was in 1671, the script dated 21st October 1668 at Quam Cheu in Quantum. "Les Secrets de la Medecine Chinoise qui Consistent en la Perfecte Connaissance du Pouls" was written by a missionary who says of himself that he had preached for three years in China and was then banished to Canton. In the introduction he explains that he writes in French (instead of Latin) in order to make the "secrets decouverts" known to everyone, "savants et ignorants".

The treatise itself consists of four parts. The first part contains instructions on how to take the pulse (50 paragraphs), the second cites rules of the pulse, the third part gives predictions about the course of the dysfunctions which are recognised by taking the pulse, and in the fourth part, Chinese medicine is evaluated and compared to other medical practices. The author comes across as a very passionate and enthusiastic person who had practised pulse diagnosis himself and believed in the power inherent in every secret knowledge.

As far as is known, one other Jesuit treatise was published in the 17th century "Clavis Medica ad Chinarum Doctrinam de Pulsibus" (1686) by the Polish missionary Michael Boym (1612-1659). This treatise is of particular interest because it contains translations of the *Neijing* and the *Nanjing*; pulse diagnosis is discussed at length. Material from other Jesuit fathers and possibly parts of Boym's text were assembled by A. Cleyer in "Specimen Medicinæ Sinicae, Sive Opuscula Medica ad Mentem Sinensium" which was published in 1682, or possibly even twenty years earlier (Pelliot 1934). Andreas Cleyer was a German doctor with the Dutch East-India Company, but his information was derived from the work of Jesuit missionaries and contained a good deal on pulse diagnosis.

It is interesting that unlike Boym's publication, Cleyer's was later repeatedly cited, thanks to floyer (1707), especially in England. Cleyer was a doctor, like Ten Rhyne, Kaempfer and floyer; it seems that doctors have tended to be aware only of other doctors' publications. Finally, the Jesuit J.B. Du Halde of the 18th century (mentioned above) needs to be mentioned for his work which contains a detailed account of TCM and more than one hundred pages of translation from Chinese medical classics including several pharmacopoeias.

In summary, the reports by the Jesuits referred to the conceptual framework determined by pulse diagnosis and the circulation of "Qi", while it was the technique of needling which caught the attention of the travelling doctors. The doctors came and went, they looked and could not really listen, and moreover their minds had been subject to years of medical training which focused and pre-structured their conceptions. Possibly the Jesuits recognised the importance of diagnosis for the practice of medicine, or more probably, they were struck by the achievements of pulse diagnosis. This seems very likely when one recalls the medical knowledge they were familiar with before they left for China. One had to admit, Jean Siu said, that the Chinese method of taking the pulse (which they did, in his opinion, because they did not know anatomy) was easier, more generally applicable and much more accurate than all the methods which had ever been described by masters and doctors of medicine in Europe (cf. Buet 1977). However the Jesuits' treatises had hardly any impact on the practice of medicine in the early 19th century.

In the 20th century, when acupuncture practice took off again, the practice was based on directly imported, but still much transformed knowledge of TCM practices in China. In view of the age old presence of Jesuits in France, one wonders how far the Jesuit tradition and its modern representatives (père Larre etc.) could have had an impact on these modern developments in France.

3. SUMMARY

In the 17th century, doctors travelled to the Far East and they reported on their observations. At the same time Jesuit missionaries were working in China. Since they were well versed in the language, they could collect and translate authentic Chinese sources on TCM, sayings of indigenous practitioners or passages of medical classics.

In the 18th century, acupuncture was either ignored or severely criticised, particularly in Germany, while a few "Grandes Oeuvres" in France included a chapter on acupuncture.

In the beginning of the 19th century, needling enjoyed an immense popularity in France which spread to its neighbouring countries. However, it vanished just as rapidly and completely as it had arisen.

In the middle of the 19th century, some fragmentary but accurate treatises on TCM reasoning were published, often as chapters of large tomes by French doctors. These treatises had often been written more than a century earlier; mainly by Jesuits. But, published or unpublished, they did not stimulate the investigation of theoretical considerations in TCM; nor did Captain Dabry's detailed and didactic work "La Médecine chez les Chinois" (1863).

The practice of acupuncture reappeared in France in the 1930's and spread from there all over Europe. This time, with some delay, the inquiry into the principles of TCM as well as into the history and development of these ideas has been widely promoted.

The above sketch points out that the assimilation of the practice of acupuncture needling and the investigations into the theory of TCM took place within two separate professional groups in Europe. On the one hand, there were doctors who reported observations of the practice of acupuncture needling: Chinese and Japanese practices during the 17th century, and European practices during the 18th and early 19th centuries. On the other hand, treatises of TCM reasoning were collected and translated mainly by Jesuits. We observe that the first treatises on TCM principles were written at the same time as the first travel reports. However crucial these treatises were for practising and understanding acupuncture, they seem to have had no direct impact on contemporaries, not even on needling practitioners. This dichotomy between the application of the technique and investigations into the theory of acupuncture and TCM has obviously had a long history, and it can still be observed in the 20th century.

Acknowledgements

I would like to thank Mr. G. Blue and Dr. V. Law for their advice and support.

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The Illinois Acupuncture Federation

- Asian American Acupuncture Association
- Illinois Association of Acupuncture and Oriental Medicine
- Korean American Acupuncture Association
- Pacific College of Oriental Medicine

Position Statement on Dry Needling in Illinois June 2011

It has come to our attention that recently the Illinois Physical Therapy Licensing and Disciplinary Committee has determined or is considering to determine that Trigger Point Dry Needling (AKA Intramuscular Manual therapy) is within the scope of practice for Physical Therapists in the State of Illinois.¹ It is the position of the Illinois Acupuncture Federation that this determination exceeds the scope of authority for any individual ILDFPR Board, and in fact represents an expansion of scope for a profession, thereby necessitating that this change be enacted via proper legislative procedure.

Rationale: Per the Acupuncture Practice Act, Section 10, "Definitions", Acupuncture is clearly defined as:

"...The evaluation or treatment of persons affected through a method of stimulation of a certain point or points on or immediately below the surface of the body by the insertion of pre-sterilized, single-use, disposable needles, unless medically contraindicated, with or without the application of heat, electronic stimulation, or manual pressure to prevent or modify the perception of pain, to normalize physiological functions, or for the treatment of certain diseases or dysfunctions of the body..."

Per the Acupuncture Practice Act, only Licensed Acupuncturists and individuals licensed under the Medical Practice Act of 1987 are permitted to practice Acupuncture in the State of Illinois. Trigger Point Dry Needling uses acupuncture needles, inserted into the body, to cause muscle fasciculation for the purpose of alleviating pain and dysfunction. Therefore, under Illinois law, "Trigger Point Dry Needling" is "Acupuncture". The practice of Acupuncture by Physical Therapists violates the Acupuncture Practice Act. Therefore, the practice of Trigger Point Dry Needling by Physical Therapists violates the Acupuncture Practice Act. Simply renaming and rebranding "Acupuncture" as "Trigger Point Dry Needling" does not make it a unique technique. (Please refer to the AAAOM position statement on this issue for more information.)

Furthermore, while the Physical Therapy Act does not specifically exclude invasive procedures, no procedure noted in the Act nor currently practiced by Physical Therapists in Illinois involves the penetration of the dermal barrier. Thus, Trigger Point Dry Needling represents the addition of a technique that is substantially different from any other

technique used in the field. This additional technique further carries with it substantial risk of patient injury in the hands of untrained practitioners, including but not limited to organ puncture and infection.

The National Chiropractic Council (NCC), a federal risk purchasing group which purchases physical therapy malpractice insurance on a group basis, states in a letter dated November 18, 2009 that this type of Board-related approval of the inclusion of this technique into the scope of practice of Physical Therapists is “not only overreaching but almost irresponsible and dangerous.” They conclude, looking at the risk/benefit ratios and the lack of supervision and established standards for training in the use of acupuncture in this manner, that, “the NCC will not provide malpractice insurance for any physical therapist who inserts needles and/or utilizes the technique of dry needling.”

While the IAF recognizes that professions often have overlap in techniques used, because of Illinois State definitions and determinations that define an entire licensed profession (“Licensed Acupuncturist”), this expansion effectively serves to remove any barriers to the practice of that profession by another professional group, who will have at best minimal if any regulation or monitoring of safety or quality. It renders meaningless the stringent requirements placed on one group to practice acupuncture (including national certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM), the completion of Clean Needle Technique training, 1500-3000 hours of training in accredited programs of Acupuncture and Oriental Medicine, and on-going maintenance of continuing education), and arbitrarily allows another group to practice should they self-determine that they are qualified.

This move to add what is by State definition “Acupuncture” to the scope of practice of Physical Therapists in Illinois opens a door to public harm and misrepresentation, and further serves to confuse the public about safeties they have come to expect and standards for practice they deserve to have in place. It underscores that while one professional group is required to demonstrate excellence and prove on-going competence in this field, another group can effectively do whatever they choose. For the protection of the public safety and for the preservation of the legal integrity of the practice act structure in Illinois, it must be beyond the scope of authority for this change to occur via Board determination alone. As stated in the very introduction to the Acupuncture Practice Act, “It is...declared to be a matter of public interest and concern that the practice of acupuncture as defined in this Act merit and receive the confidence of the public, and that only qualified persons be authorized to practice acupuncture in the State of Illinois.” This allowance sabotages any semblance of confidence. The practice of Acupuncture by Physical Therapists, by whatever name is being used for the procedure, should cease and desist.

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¹ <http://www.idfpr.com/Forms/Professions/031511PTAGMEMO.pdf>

Reflections on the German Acupuncture studies

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Keywords:
German
acupuncture
trials; sham
acupuncture;
GERAC, ART.

Abstract

The author discusses the recent German acupuncture trials showing how there remain difficulties in understanding their results. Among these are unresolved questions about the acupuncture/sham acupuncture interventions, and the issue of whether their results can be generalised outside of the practice of acupuncture as an adjunctive treatment by physicians.

Clinical research into acupuncture can be a critical aspect of how acupuncture is accepted by society. A number of large controlled trials of acupuncture have been undertaken in Germany, some of which have been recently published [Diener et al. 2006, Linde et al. 2005, Melchart et al. 2005, Scharf et al. 2006, Witt et al. 2005]. Several of these studies are perhaps the largest controlled trials to date of acupuncture [Haake et al. 2003, Streng 2007]. It is thus important to fully understand the results and their implications. Trials of acupuncture have been plagued by problems in the past, making interpretation of their results often difficult. Below I discuss how problems with these large trials also make such interpretation difficult.

When clinical research studies are undertaken it is important to know why the studies were done and for whom. Sometimes the reasons and target audience for a study become confused as researchers try to answer different questions for different reasons in the same study. Additionally, in acupuncture trials there have been calls for many years to ensure that the tested treatment is valid and that an appropriate control is used, with various recommendations about study design requirements depending upon the type of question and study. It is my contention that these big German acupuncture studies on low back pain, migraine, tension headache and osteoarthritis of the knee raise many questions and give rise to contradictory interpretations of results, lingering controversies and unresolved questions.

Why were the studies done? Acupuncture has historically been paid for by the social insurance system in Germany, provided that it is administered by a physician who meets the minimum training required by the association the doctor is a member of. There have been as many as 20,000-50,000 physicians using acupuncture in their practices in Germany as a result of this [Streng 2007]. The so-called GERAC

studies and those done through collaboration between Munich and Berlin based research groups (ART studies) were initiated because of a desire to maintain national insurance coverage for acupuncture in Germany [Ernst 2004, Haake et al. 2003]. The social insurance system had declared acupuncture of questionable effectiveness and stated their intention to stop paying for it. In response to this, negotiations between the physician acupuncture groups and these authorities decided that acupuncture could still be paid for provided the patient was being treated for one of four medical conditions and that the patient was enrolled in a trial of acupuncture for that condition. The four medical conditions that were judged to have a promising evidence base were low back pain, migraine, tension headache and osteoarthritis of the knee [Stux G, personal communication, Molsberger A, personal communication]. But even this is somewhat controversial. For example, one German physician reports participating in an early meeting about the trials where the stated reason for the trials was quite different: the insurance companies wanted to make compensation for acupuncture treatments part of a package, resulting in significantly less payment per treatment for the physician. Many physicians did not want this and, after negotiations, these studies were the result [Prost C, personal communication]. Further, the judgment about which four medical conditions to focus on is also somewhat controversial. When these four medical conditions were chosen because they had sufficient evidence to warrant further investigation for their inclusion in future insurance reimbursement, the clinical trial evidence for acupuncture had drawn different conclusions. At that time only two medical conditions (nausea and vomiting and post operative acute dental pain) had demonstrated treatment effectiveness in trials [Acupuncture 1998, Birch et al. 2004, BMA 2000], neither of which has been included in either trials or the new insurance coverage in

Germany. Several other conditions showed similar levels of positive evidence such as temporomandibular disorder, stroke rehabilitation, fibromyalgia [Birch et al. 2004] yet these were not included in the German studies. At the time of these discussions in Germany, systematic reviews had drawn contradictory conclusions regarding osteoarthritis of the knees, low back pain and migraine, with single studies drawing tentative positive conclusions, but other studies not, while the evidence for tension headache has lagged behind those three [Birch et al. 2004]. The decision of what conditions to focus on have been made partly on scientific grounds and partly socio-political grounds.

There are clear study designs for answering questions that arise on socio-political grounds. Typical questions and models are: How effective is acupuncture compared to standard care? [e.g. Carlsson, Rosenhall 1990]. How effective is acupuncture in addition to standard care compared to standard care? [e.g. Hu et al. 1993]. How effective is the offer of acupuncture compared to not offering it? [e.g. Eisenberg et al. 2005, Vickers et al. 2004]. How cost effective is acupuncture? [Ratcliffe et al. 2006, Wonderling et al. 2004]. These questions are of particular socio-political interest and compare acupuncture to no treatment or a standard treatment [Thomas, Fitter 2002].

The German federal committee that decided on these studies required the inclusion of sham arms in the trials [Streng 2007] which answers a different type of question: how effective are the active ingredients of acupuncture treatment? This kind of question is generally thought to be of interest to academics [Haselen 2005] and uses a sham comparison design intended to control for placebo effects [Thomas, Fitter 2002]. This is important because the use of the acupuncture versus no treatment or standard treatment has been widely used outside of Germany in reimbursement related trials in the US and UK [Cherkin et al. 2001, Eisenberg et al. 2005, Thomas et al. 2006, Vickers et al. 2004, Wonderling et al. 2004] and is usually thought to be the preferred design for this kind of question [Thomas, Fitter 2002]. The GERAC and ART studies ended up using a three-arm design where acupuncture was compared to sham acupuncture and a wait-list or standard therapy. They tried to address scientific and socio-political questions at the same time. Unfortunately the requirements of the two study designs, acupuncture versus sham acupuncture and acupuncture versus no or standard treatment are quite different. In normal clinical studies of drugs, these are not such huge issues, but in acupuncture studies, where design issues are far more complex, these designs do not fit well, if at all, together. In the acupuncture versus no or standard therapy design, the acupuncture can be

The training requirements for acupuncture vary considerably according to who is practising it, in what context and as part of what overall system of health care. This makes it quite difficult to generalise results of acupuncture practice in one situation to practice in other situations

more natural, less constrained and as real-world as possible, with minimal limitations on the techniques that are applied and no concern about interactions between the therapist and his staff with the patient [Thomas, Fitter 2002]. In the acupuncture versus sham comparison, studies tend to a very constrained model with more rigid treatment protocols and complex requirements to maintain the blinding [Thomas, Fitter 2002]. They also have to pay considerable attention to the interactions between patient and therapist and his staff so that they can limit and attempt to control for the non-specific effects that arise in clinical practice [Birch 2004, Lewith, Vincent 1996, Margolin et al. 1998, Vincent, Lewith 1995]. These are contradictory approaches for a study. Naturally, the researchers conducting these studies attempted a compromise, thereby introducing potentially fatal flaws and leaving us with difficulty in interpreting the results. For example, the ART study on tension headache was proclaimed to be a success for acupuncture since both the acupuncture and sham were significantly more effective than standard therapy [Melchart et al. 2005], and similarly for the ART migraine study [Linde et al. 2005]. On the other hand, others outside of Germany have proclaimed these studies very negative for acupuncture since acupuncture was not more effective than the sham [Ernst 2004, Henderson 2005]. On the surface it seems that both interpretations are correct since the first is related to the more socio-political insurance question and the second to the more academic question [Haselen 2005].

However, appearances are deceptive. The second major problem with these studies lies in the question: what is acupuncture? This is a complex question as its practice varies in different countries and among different traditions and practitioners [Birch Felt 1999, Birch, Kaptchuk 1999, MacPherson, Kaptchuk 1997]. Sometimes it is used as a stand-alone complete medical system, sometimes as part of a complete medical system alongside, for example, herbal medicine, and sometimes it is used simply as a technique, added by medical personnel to their treatment toolbox [Birch, Felt 1999]. The training requirements for acupuncture vary considerably according to who is practising it, in what context and as part of what overall system of

health care. This makes it quite difficult to generalise results of acupuncture practice in one situation to practice in other situations. In some countries, such as China, the US, Japan and parts of Australia, acupuncture education is regulated by government established or approved agencies. There are minimum standards of education required for different kinds of practitioners. In other countries regulation of training is more internally controlled: to join organisation X one must meet its minimal educational requirements after which one can enjoy the benefits of being a member of that organisation, for example insurance reimbursement of treatment. This is the situation for acupuncture when practised by physicians in Germany.

In analyses of the treatments that were provided in two of the ART studies, the researchers acknowledged that an important percentage of the participating acupuncturists felt that they would have performed the treatments differently than they were allowed by the study design

The World Health Organisation in consultation with numerous international acupuncture organisations (medical and non-medical) developed international educational guidelines for acupuncture [WHO 1999]. For any non-physician to practise acupuncture they recommend a minimum of 2,500 hours of study (including 1000 hours of biomedical studies). For a physician who wants to work primarily as an acupuncturist they recommended a minimum of 1,500 hours of acupuncture study and for physicians who want to use acupuncture techniques in their medical practice, they recommend not less than 200 hours of acupuncture study [Moir 2007a]. Of course these are guidelines only, but they are relevant when we look at how acupuncture was tested in the German studies, the probable training of the practitioners in these clinical trials and how well these results generalise to the practice of acupuncture elsewhere.

Up until a few years ago in Germany there was a general agreement that for physicians to join one of the major acupuncture organisations and get insurance reimbursement, a minimum of 130 hours of acupuncture education was required. Over the last years this number was increased in some groups to 350 hours [Stux G, personal communication], more recently called the a-level and b-level licenses [Streng 2007]. But the issue of the number of hours of basic training in acupuncture required by organisations has been contentious. Understandably many would

rather do the minimum necessary since they only use acupuncture occasionally as an auxiliary technique in their medical practice. It is thus rather convenient for those arguing for less hours of training that the acupuncture did not outperform the sham acupuncture as it supports their argument. Did this issue play any role in the trials and how the participating physicians performed their treatments?

The various studies conducted in Germany recruited physicians from among the professional organisations to perform the acupuncture. In the GERAC low back pain study, as many as 50 physicians in private practice were recruited [Haake et al. 2003], a similar number were recruited for the GERAC migraine study [Stux G, personal communication] and 320 for the knee osteoarthritis study [Scharf et al. 2006]. The basic training of many of these will have been similar to or less than that recommended by the WHO for a physician who wants to use acupuncture as an auxiliary technique within their medical practice. Further, some of the studies attempted to provide 'TCM' type acupuncture [e.g. Haake et al. 2003, Stux 2007]. The minimum training programmes to learn 'TCM' acupuncture involve many hundreds of hours of study. Acupuncture programmes in the UK and Canada are a minimum of 1,200 and 1,900 hours of study respectively, while acupuncture and TCM programmes in the US, Australia and New Zealand are a minimum of 2,625, 2,500 and 3,600 hours respectively [Moir 2007b]. The numbers in Japan recently were a minimum of 2,235 hours [Birch, Ida 1998:305-307]. If the physicians who performed the acupuncture in these studies had completed the basic training required in Germany to join one of the associations, it is quite probable that they were not trained in TCM sufficiently to be able to make full TCM diagnostic decisions and apply treatment accordingly. Furthermore, in analyses of the treatments that were provided in two of the ART studies, the researchers acknowledged that an important percentage of the participating acupuncturists felt that they would have performed the treatments differently than they were allowed by the study design [Linde et al. 2006, Melchart et al. 2005]. Some of the participating practitioners [24% - Melchart et al. 2005, 20% Linde et al. 2006] thought that the number of treatments may not have been enough. These complex issues lead to two questions.

Were all the participating acupuncturists adequately trained? It is possible that some of the participating physicians were not sufficiently equipped to perform the TCM acupuncture treatments they were asked to perform. Although some see them as having been well trained [Baeker et al. 2007], others have questioned this [Stux 2007]. An important number

of participants wanted to apply more treatment but were constrained by study design. Many in the non-physician community, who use acupuncture as a complete system of therapy rather than as just an adjunctive technique within a medical practice, have questioned how well prepared the participating practitioners really were [Stux 2007]. This leads to the second question.

Can we generalise these results beyond the practice of acupuncture by physicians trained only to use acupuncture as an adjunctive technique within general medical practice? Can we proclaim that acupuncture does or does not work? I think not. It is necessary to state clearly what was done; the nature of the acupuncture given, by whom and how the results relate to that alone and not attempt to make grandiose statements [Ernst 2004] about acupuncture. I believe that all we can say is that when physicians trained to use acupuncture techniques in their medical practice compared such treatments to techniques they were unfamiliar with (the sham - more on this below), they could produce no difference in results between their chosen treatments and sham treatments and that both forms of 'acupuncture' were generally better than or equal to the treatment they usually provide for the same conditions. Although it is difficult to interpret this finding, it certainly does not sound the death knell of acupuncture as some would try to have us believe [Ernst 2004].

The next major issue with the study was the sham acupuncture. Sham interventions are usually used in order to control for placebo effects so that the specific effects of the therapy can be examined. However, as the study authors acknowledge [Linde et al. 2005, Scharf et al. 2006], their sham (minimal acupuncture) is an active sham and is not a placebo treatment. I need to emphasise this because many that see a sham controlled study reflexively interpret it as a placebo controlled study. Thus when, in this case, acupuncture did not outperform the sham, it is seen as meaning it was no better than placebo. This conclusion is not valid and cannot be drawn from sham acupuncture studies unless particularly difficult procedures are also followed [Birch et al. 2002, Birch 2004, 2006-a]. Any sham technique that is not inert needs to have been investigated in pilot studies so that one can determine what it is capable of doing and to ensure that it is not (unbeknownst to the researchers) a highly active treatment [e.g. Wyon et al. 1995, see Birch 1997 and Medici et al. 2003, see Birch 2003a]. There is no evidence of pilot studies having been conducted in these German studies [e.g. Haake et al. 2003, Melchart et al. 2005]. Hence these studies potentially suffer from a double fault with regards to the two types of acupuncture treatment given: i. the acupuncture treatments that were provided may have fallen short on adequacy through the variability and nature of the training of the participating physicians, and ii. these treatments were compared to sham acupuncture treatments of unknown physiological

and clinical effectiveness. Perhaps this is why some study authors concluded: "Our observation raises the question of whether there is a single optimal point selection and whether deep needling with stimulation and deqi is superior to shallow needling" [Scharf et al. 2006]. Besides these questions, the issue of whether one can generalise from studies where acupuncture was used primarily as an adjunctive therapy in medical practice to the general practice of acupuncture still remains.

Some people reading these studies have noted that the lack of significant difference between the 'real' and 'sham' arms of the trials implies that it does not matter where one inserts the needles and that thus the theories of acupuncture are unnecessary [Ernst 2004]. This is an invalid conclusion. In order to answer questions about site specificity, or the relative role of the sites at which the needles are inserted, it is necessary to apply the same techniques to both those sites and the control sites [Baecker et al. 2007, Birch 2003]. This was not done in these studies. Both the sites of needle insertion and types of needling varied.

Finally, there are questions concerning recruitment. Patients were generally recruited out of the practice of participating physicians. For a social or economic comparison study this is a proper recruitment strategy, but for a sham study it makes it virtually impossible to guarantee that all the strict requirements needed for sham studies were followed [Margolin et al. 1998]. Because the therapist is not blind to treatment assignment, it is important to keep the therapist out of all communications with the patient except for those necessary for the correct administration of the treatment. It is very difficult to eliminate the possibility of unintended communication when the therapist is involved in patient selection and screening, treatment assignment, setting up the study with the patient and administering the treatments. [Margolin et al. 1998] A second problem concerns how strictly the inclusion-exclusion criteria were applied and monitored. In the original idea of the studies, patient treatments were to be paid for by the insurance companies if the patient was treated for one of the four conditions studied and was enrolled into the relevant study. In fact reimbursement would continue only for patients with one of these problems, provided they participated in the studies. The Munich-Berlin group conducted a number of lesser controlled studies to examine adverse effects [Melchart et al. 2004], epidemiological factors [Linde et al. 2006, Melchart et al. 2006] and cost effectiveness [Witt et al. 2006]. This allowed the research teams to include huge numbers of patients in the various studies. Given how patient recruitment was performed in these studies, can we be sure that physicians wanting to treat a patient with another medical problem (such as menstrual pain or IBS) did not enroll the patient into one of the studies because they also complained of one of the four symptoms, thereby

ensuring that their treatments would be paid for? This is unlikely in the ART studies where participating physicians could refer patients into the larger lesser controlled studies. But it is likely to be more of a problem for the GERAC studies where the studies did not offer this out to the participating physicians. From the study descriptions, it appears that recruiting physicians applied the inclusion-exclusion criteria themselves to patients in their practices, without the presence of an independent observer which is necessary to ensure proper application of inclusion-exclusion criteria [Birch, 2004, Margolin et al. 1998]. Although there was periodic external monitoring, this cannot exclude inadvertent problems.

It is difficult to generalise the results of these studies outside the practice of acupuncture as adjunctive therapy in medical practice.

In summary, I believe that the design used in these studies makes contradictory interpretations possible. It looks as though some or all of these studies may have suffered from problems with the training of the acupuncturists, adequacy of treatments and importantly, use of an unvalidated and untested sham. These issues make interpretation of the real-sham comparisons difficult. It is difficult to generalise the results of these studies outside the practice of acupuncture as adjunctive therapy in medical practice. Further the strict requirements for a sham acupuncture study were either not followed and/or not well monitored or regulated; there are issues around recruitment methods, treatments settings, blinding of key study personnel and monitoring of these. However there remains the puzzling finding that when physicians used acupuncture in these trials, regardless of what treatment they did, the acupuncture was generally as or much more effective than the standard therapy. This is difficult to explain.

As a result of these studies, acupuncture is now paid for in Germany by the social insurance scheme if administered by a qualified physician for chronic low back pain and osteoarthritis of the knee, but not tension headache or migraine [Bovey 2006, Streng 2007]. This decision was made partly on the results of the studies and partly for socio-political reasons [Streng 2007]. Thus these studies have started to affect delivery of acupuncture in Germany. It remains to be seen how the international community deals with them. What impact will they have on insurance reimbursement outside of Germany? Will the fact that specific German socio-political factors influenced the choice of study, their design and the interpretation of

results be taken into account by scientists and health care analysts in other countries? How will they be interpreted in systematic reviews and what effect will they have on the conclusions and potential applications of those systematic reviews [Birch 2007]? Have these studies exposed problems with how acupuncture is understood to work? If so will this trigger demands for more studies investigating specific effects using 'sham controlled' trials or have they finally demonstrated the inherent difficulty of conducting them [Birch 2006-b]? Is it now time to acknowledge that placebo, rather than being a nuisance variable in clinical trials, is a poorly constructed term that captures some of the ways that the body heals itself and thus maybe should not be controlled for? Answers to these questions will only emerge over time. ■

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Is MediPuncture the same as Acupuncture



Categories

› Uncategorized

Archives

› August 2014

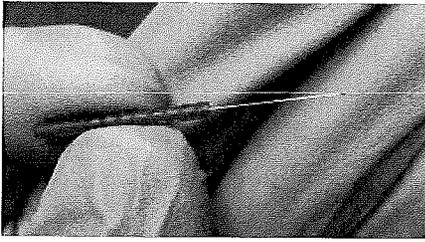
There is sometimes confusion about how dry needling including MediPuncture differs from Traditional Chinese Medicine (TCM) Acupuncture. The confusion originates as a result of the same tool being used by dry needling practitioners as by TCM acupuncture providers.

This is a tool. It is a wrench. It is used by mechanics, electricians, plumbers and homeowners.

When using this tool to tighten loose water valves, the use of this tool is plumbing.

When used to loosen nuts on a starter in a car engine, the use of the tool is auto repair.





This is a tool. It is a needle.

This tool is used by professionals that perform TCM acupuncture. It is also used by professionals that perform dry needling. This is the tool that is used to perform MediPuncture.

The use of the tool does not define the practice that is being performed.

Although the tool being used by practitioners performing MediPuncture or other forms of dry needling is the same tool that is used by TCM acupuncture providers, dry needling, including MediPuncture, is not the same as TCM acupuncture.

Dry needling professionals including chiropractors, physical therapists, medical doctors, and others use the needle to stimulate specific neurological points and target muscle tissue that have been selected based on Western medical criteria. The use is to help injured tissues heal and to resolve neurological sources of chronic pain.

TCM acupuncture providers use the tool to stimulate theoretical energy meridians. The selection of the points used in TCM acupuncture is largely based on the concept of blocked flow of energy through the energetic meridians.

Although the two practices may look similar, the differences in the details are quite substantial.

MediPuncture can be used by licensed acupuncturists, since they are authorized to insert needles into the patient for therapeutic benefit. However, MediPuncture is a dry-needling technique. Even when it is used by acupuncturists it is not used in the same way as TCM acupuncture. Similarly, acupuncturists may use modalities such as electrical stimulation. Though electrical stimulation is a tool used in physical therapy and chiropractic care, the use of electrical stimulation in itself does not define those professions.

MediPuncture can also be used by any health care professional that is licensed by his or her state to use therapeutic dry needling... if that professional has taken the training specific to MediPuncture. MediPuncture is a specific application of therapeutic needling intended to affect the neurological status of a person or to directly affect injured tissue or tissue in a pathological state to initiate healing activity.

TCM acupuncture originated in China thousands of years ago before the nervous system or pathology of tissues were understood. It is said that the practice originated during the pre-scientific period. The theories of acupuncture are not based in any way upon contemporary understanding of how human physiology works.

MediPuncture, like other forms and styles of dry needling therapy, originated in the United States in the modern age. It is soundly based on scientific concepts.

Dry needling is practiced by a wide range of professionals that have been trained in Western medicine principles of anatomy, neurology, physiology, kinesiology, biochemistry and other basic life sciences.

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sensors, electric
impedance meters,
location and
proximity devices in
the nature of
electrical signal
sensors, electronic
frequency sensors,
radio frequency
detectors, magnetic
field sensors, and
electromagnetic
imaging sensors,
and electromagnetic
field detectors, joint
dimension
measuring devices
in the nature of
goniometers for
medical use,
auscultation devices

in the nature of stethoscopes, medical devices for measuring and recording joint function, medical devices for recording and measuring muscle function, algometers and blood pressure testing apparatus; patient treatment tables; positioning devices in the nature of foam positioning pads for medical and physical therapy use

Goods and Services

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Goods and Services

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instruction and training of others in the field of dry needling and distributing course materials in connection therewith; Providing medical education services in the nature of medical training and teaching to professionals in the field of dry needling

Goods and Services

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MEDI PUNCTURE

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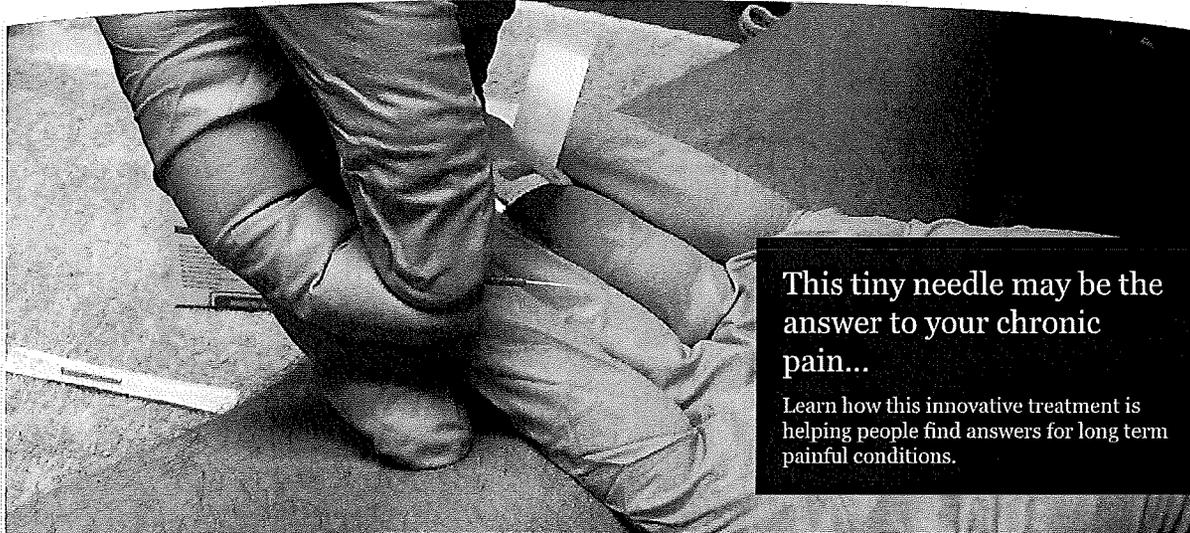
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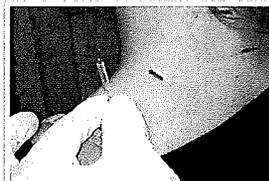
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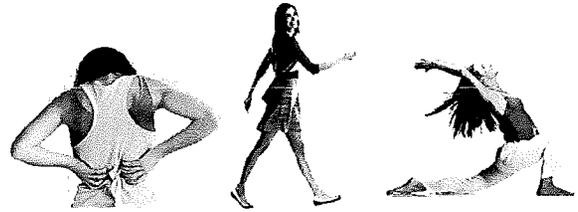
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Frequently Asked Questions

Question 1: I have heard of trigger point dry needling or have already taken a course in trigger point dry needling. How is Intramuscular Stimulation - IMS trigger point dry needling different from other forms of trigger point dry needling?

Answer: IMS trigger point dry needling is based on a neuroanatomic and pathophysiological model of myofascial trigger point pain that provides a rationale for the physical examination of the patient which forms the basis for treatment. Students will be taught how to evaluate and select appropriate patients for treatment based on this model, and how to integrate postural exercise, manual therapy and electro-therapeutics into a comprehensive rehabilitation program. The value and limitations of MRIs and EMG studies in this patient population will be discussed.

Like dry needling, IMS dry needling uses a fine gauge monofilament needle, but attaches the needle to a holder-plunger device that transforms it into a precisely controlled tool. This needle holder-plunger instrument provides a number of advantages over the traditional needle guide-tube technique. First, it allows the practitioner to very accurately and quickly locate the muscle contractures associated with trigger points that must be treated, including deep ones. The proprioceptive feedback that the instrument provides to the practitioner allows for controlled advance of the needle over very small distances, thereby facilitating discernment of needle location as well as tissue consistency and type (normal muscle vs. abnormal muscle vs. connective tissue). These in turn lead to the safe and efficient treatment of a large number of trigger points in each treatment session, thus promoting quicker rehabilitation of the neuromuscular unit. Lastly, unlike the guide-tube technique, the holder-plunger prevents the needle from bowing while being advanced, and so keeps it from bending or heading off of its intended direction. As a result IMS can use finer gauge needles that minimize patient discomfort.

IMS trigger point dry needling is therefore highly effective in safely and efficiently reducing pain and restoring normal range-of-motion while leading to true functional rehabilitation.

Question 2: Is the LearnIMS Course an approved or accredited course in post-graduate instruction and training in trigger point dry needling that satisfies state and county requirements/prerequisites necessary to legally perform dry needling?

Answer: NO. Each state and county has its own regulations for healthcare providers and it is the participant's responsibility to know the laws, rules and regulations for their license and the location of practice. The LearnIMS Course is NOT approved or accredited by any state or county licensing or regulatory health agency or entity, and it is the responsibility of the participant to determine and ensure that employment of IMS is within the scope of practice for their professional license and the jurisdiction within which they employ it and that they have satisfactorily completed all prerequisite accredited courses/training required by the governing health care authorities of that jurisdiction

Steven R. Goodman, M.D., P.S., Inc and LearnIMS are NOT responsible for the implementation of the technique the student will be trained in, the laws and regulations the participant is bound by, or how the participant chooses to utilize the technique if it is outside the guidelines in which they were trained.

Question 3: Are continuing education credits (Continuing Medical Education/CME, Continuing Education/CE) offered by the LearnIMS Course?

Answer: NO. The LearnIMS Course is NOT accredited by any medical or physical therapy organization for continuing education credits. Upon successful completion of the course you will be given a certificate indicating that you have completed twenty-seven (27) hours of advanced instruction in IMS, a form of trigger point dry needling. You may independently apply to your state licensing board for continuing education credits, and LearnIMS will provide additional verification of successful completion, course syllabus and Dr. Goodman's CV if requested in writing.

Question 4: If the state and county jurisdiction where I practice does not include dry needling in the scope of practice for physical therapists can I still take the LearnIMS Course?

Answer: Yes, you may take the LearnIMS Course but it is your responsibility to know the laws and regulations for the state and county where you practice. If trigger point dry needling is NOT within the scope of practice where you practice, completion of the LearnIMS Course will NOT make it legal for you to practice dry needling in that jurisdiction.

Question 5: At the completion of the LearnIMS Course will I be able to immediately return home and begin using IMS dry needling in my practice?

Answer: The goal of the LearnIMS Course is to provide you with all of the education, technical instruction, supplies, and support material to safely and competently perform IMS dry needling immediately upon its completion. You may however ONLY employ IMS dry needling immediately upon completion of the LearnIMS Course IF dry needling is within the scope of practice for your profession where you practice AND you have satisfied all prerequisite accredited courses required by your state and county health care licensing and regulatory authorities.

Question 6: Is IMS dry needling an insurance reimbursable procedure?

Answer: IMS dry needling is reimbursable by some but not all insurance. It depends on where you practice and the specific insurance and plan. More information on billing for dry needling can be found at: <http://www.apta.org/StateIssues/DryNeedling/>

Question 7: What types of conditions/diagnoses will I be able to treat upon completion of the LearnIMS Course?

Answer: You will be able to successfully treat common conditions including neck and low back pain, rotator cuff tendonosis, lateral and medial epicondylosis, tension headache, gluteal bursitis, iliotibial band syndrome, runner's knee, Achilles tendonosis, and others.

Question 8: What is the cost of the supplies necessary to provide IMS?

Answer: You will be provided with one (1) metal IMS plunger and fifty (50) monofilament needles as part of your course registration fee. If properly taken care of the plungers can last many years. Additional plungers cost \$70-100. Additional needles cost on average \$15.00 for one hundred (100) needles. During a typical IMS treatment you may use as few as one (1) needle and infrequently as many as five (5), typically (2-3). You will be provided with a list of suppliers for both plungers and needles.

You will also need a sharps container, latex or nitrile gloves, alcohol wipes, facial tissue, a stainless steel disinfecting tray, anti-bacteria/virucide solution and paper instrument steri-paks. These can all be obtained through any hospital/medical supply catalog.

Question 9: When and where are LearnIMS courses held?

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ARTICLE in AMERICAN JOURNAL OF PHYSICAL MEDICINE & REHABILITATION / ASSOCIATION OF ACADEMIC PHYSIATRISTS · MAY 2009

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Myofascial Pain

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Disclosures:

None.

0894-9115/10/8902-0133/0
*American Journal of Physical
Medicine & Rehabilitation*
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DOI: 10.1097/PHM.0b013e3181a5b1bc

Remote Effects of Dry Needling on the Irritability of the Myofascial Trigger Point in the Upper Trapezius Muscle

ABSTRACT

Tsai C-T, Hsieh L-F, Kuan T-S, Kao MJ, Chou L-W, Hong C-Z: Remote effects of dry needling on the irritability of the myofascial trigger point in the upper trapezius muscle. *Am J Phys Med Rehabil* 2010;89:133–140.

Objective: To investigate the remote effect of dry needling on the irritability of a myofascial trigger point in the upper trapezius muscle.

Design: Thirty-five patients with active myofascial trigger points in upper trapezius muscles were randomly divided into two groups: 18 patients in the control group received sham needling, and 17 patients in the dry-needling group received dry needling into the myofascial trigger point in the extensor carpi radialis longus muscle. The subjective pain intensity, pressure pain threshold, and range of motion of the neck were assessed before and immediately after the treatment.

Results: Immediately after dry needling in the experimental group, the mean pain intensity was significantly reduced, but the mean pressure threshold and the mean range of motion of cervical spine were significantly increased. There were significantly larger changes in all three parameters of measurement in the dry-needling group than that in the control group.

Conclusions: This study demonstrated the remote effectiveness of dry needling. Dry needling of a distal myofascial trigger point can provide a remote effect to reduce the irritability of a proximal myofascial trigger point.

Key Words: Dry Needling, Myofascial Trigger Point, Pain Intensity, Remote Effect

In the past two to three decades, dry needling has been widely used for patients with acute or chronic muscle pain.¹⁻¹¹ The mechanism of therapeutic effectiveness is still unclear, but it is probably similar to acupuncture for pain control (hyperstimulation analgesia).⁷⁻⁹ Based on the studies on myofascial trigger points (MTrPs) in both human subjects and animals, it is hypothesized that the needling effect on MTrPs is mediated via spinal cord reflexes.^{5,12,13} An MTrP has been defined as a highly localized hyperirritable spot in a palpable taut band of skeletal muscle fibers characterized by typical referred pain pattern and local twitch response (LTR, a sudden forceful contraction of a group of muscle fibers in a taut band).¹¹ An active MTrP is the one with spontaneous pain, whereas a latent MTrP is painful (tender) only when it is compressed.¹¹ High-pressure stimulation, such as needling, to an MTrP can elicit referred pain and LTR.¹¹ There is evidence to suggest multiple loci in an MTrP region.⁶ These loci are sensitive to pressure stimulation, which can elicit pain, referred pain, and an LTR. In dry-needling therapy, the tiny needle tip can provide high pressure to the sensitive locus in an MTrP region and can elicit a pain, a referred pain, or even an LTR.^{2,4,5,14} It is critical to elicit LTRs during needling to obtain an immediate and complete pain relief.^{2,5}

In a recent study based on the measurement of endplate noise in the MTrP region, Hsieh et al.¹⁵ have found that dry-needle-evoked inactivation of a primary (key) MTrP could inhibit the irritability of its secondary (satellite) MTrPs situated in its zone of pain referral. It has been documented that secondary MTrPs are usually located within the referred zone of a primary MTrP.^{6,11} A referred pain pattern is related to the connections between various neurons in the spinal cord.^{8,9} Therefore, a change in the irritability of a key MTrP can influence that of its satellite MTrPs. The study by Hsieh et al. shows evidence of "proximal-to-distal" influence of dry needling. The remote effectiveness of acupuncture has also been documented in the literature.¹⁶⁻¹⁹ In most cases, it is a "distal-to-proximal" influence of dry needling. The mechanism is still unclear. In this study, we attempted to assess this distal-to-proximal inhibitory effect of dry needling based on both subjective and objective assessments, including the electrophysiological measurement on endplate noise.

MATERIALS AND METHODS

General Design

Patients in the control group were treated with sham needling on the MTrP of the extensor carpi radialis longus muscle, and those in the experi-

mental group were treated with dry needling of the same muscle. Subjective pain intensity and pressure pain threshold of the upper trapezius muscle, and the range of motion (ROM) of the neck side bending to the contralateral side were measured before and immediately after the treatment. Both patients and evaluators were blinded to the group assignment.

Patients

Patients with unilateral shoulder pain caused by an MTrP in the upper trapezius muscle and who had never received treatment with MTrP needling were recruited for this study. Digital compression of this selected MTrP in the upper trapezius could reproduce the usual complaint (recognition of shoulder pain) of the patient. Thirty-five patients were selected consecutively from a pain clinic of a teaching hospital. They were randomly assigned into two groups using a computerized randomization program: the sham-needling (control) group and the dry-needling (experimental) group. Before the study, every patient had signed the consent form, which was approved by an institutional review board.

The exclusion criteria for selecting patients included (1) having any contraindication for needling of the extensor carpi radialis longus muscle, such as local infection, local trauma, taking anti-coagulant medicine, or pregnancy with threatened abortion; (2) having any problem that might interfere with the assessment of pain or pain threshold, such as substance or alcohol abuse, cognitive deficit, or communication disorder; (3) having had any previous surgery to the neck and upper back; (4) having any history of neurological deficit, either central or peripheral neurological lesions; and (5) having any other serious medical problem.

For each patient, the selected active MTrP in the painful upper trapezius muscle and the latent MTrP of the extensor carpi radialis longus muscle were identified and marked for this study. An MTrP usually can be identified by palpation of the most tender spot in a taut band of muscle. The selected MTrP of the upper trapezius muscle was located in the middle of the more nearly horizontal fibers of the upper trapezius (TrP 2 in the chart of "Travell and Simons' Trigger Point Manual"¹¹) and that of extensor carpi radialis longus muscle at proximal forearm ~3-4 cm distal to the lateral epicondyle. The diagnosis of an MTrP was based on (1) a most sensitive (tender) spot in a palpable taut band and (2) recognized pain (per patient's usual clinical complaints) when the sensitive spot is compressed.²⁰⁻²² Other supportive criteria for diagnosis included (1) a typical referred pain pattern as described by Simons and Travell¹¹ and (2) an

LTR elicited by snapping palpation of a taut band in the MTrP.

Assessment of Pain Intensity

Before needling, all patients had spontaneous pain in the involved shoulder with the most painful spot in the MTrP of the upper trapezius muscle. The subject was requested to report the pain intensity of the MTrPs in the upper trapezius muscle before and immediately after the needling therapy. Pain intensity was assessed by verbal reporting of numerical pain scale in a range from 0 to 10, with 0 representing no pain and 10 representing the worst imaginable pain. Pain with an intensity below 5 was considered to be tolerable according to our clinical experience.

Assessment of Pressure Pain Threshold

For each patient, the pressure pain threshold of the marked MTrP of the upper trapezius muscle was measured by a well-trained assistant who was blind to the procedure of treatment. A pressure threshold algometer was used for the measurements.²³ The procedure of pain threshold measurement recommended by Fischer^{23,24} was applied in this study. First, the procedure was explained clearly to the patient. Then the patient was placed in a comfortable sitting position with complete relaxation through the whole course of measurement. The algometer was applied on this marked area with the metal rod perpendicular to the skin surface. The pressure of compression was increased gradually at a speed of ~1 kg/sec. The patient was asked to say "PAIN" as soon as any increase in pain intensity or discomfort occurred. The compression was stopped when the subject said "PAIN." The subject was asked to remember this level of pain or discomfort and to apply the same criterion for the next measurement. The subject might demonstrate pain by pulling away or grimacing, which indicated that the pain threshold had been exceeded. If this was the case, the subject was given instructions again, and the measurement was repeated to ensure that the "real" threshold was obtained. Three repetitive measurements at an interval of 30–60 secs were performed at each site. The average value of the three readings (expressed as kilograms per square centimeter) was taken for data analysis of the pressure pain threshold measurement.

Assessment of ROM

For the measurement of ROM, the patient was placed in a comfortable standing position with the neck in the neutral position. The angle of contralateral side bending of neck was measured by a goniometer with big scales, which was fixed on the wall at a height so that the center of the goniom-

eter was at the spinous process of the C7 vertebra. An indicator was fastened perpendicularly around the forehead and occiput by a micro fastener. This indicator would point to the angle scale showing the degree of neck side bending when the patient bent the neck to the side. To measure the maximal active ROM, the patient was asked to bend the neck toward the nonpainful side as much as possible without moving the trunk.

Procedure of Dry Needling

The procedure of dry needling for this study was similar to that of MTrP injection as described by Hong.^{5,6} The MTrP of the extensor carpi radialis longus muscle was identified by palpation of the taut band and the most tender spot. This identified spot (MTrP region) was then compressed firmly by the index finger or middle finger of the nondominant hand to direct the placement of the needle tip. A 5-ml syringe connected with a 25-hypodermic needle (0.5 mm in diameter), 1½ inch in length, was held by the dominant hand. Initially, the needle penetrated into the skin at a point above the taut band, ~1 cm from the MTrP region. After penetration of the needle into the subcutaneous layer, it was kept there and directed obliquely to the MTrP region under the fingertip of the nondominant hand. Then the needle was inserted rapidly into the MTrP region and withdrawn rapidly. In this way, LTRs could be easily elicited because of the high-pressure stimulation generated by the rapid needle movement. The rapid needle movement could also avoid any side movement of the needle that may side cut the muscle fibers. The needle insertion was repeated many times in an attempt to elicit as many LTRs as possible, until no more LTRs could be elicited. Usually 1–2 mins were required for the complete procedure in each MTrP region. In this way, LTRs could be elicited from all MTrPs treated with dry needling. As soon as the needle was pulled out of skin, the MTrP region and the open wound of the needle insertion site were compressed firmly for about 3 mins to avoid excessive bleeding.

Regarding the procedure of sham needling, the needle penetrated the skin into the subcutaneous layer over the MTrP region of extensor carpi radialis longus muscle. Then the needle was moved in the same manner and at the same speed as with dry needling but of a different depth so that the needle tip was maintained in the subcutaneous tissue without further penetration into the muscle tissues.

Either dry needling or sham needling was performed by a physiatrist who had experience in MTrP injection for >10 yrs.

TABLE 1 Demographic data of patients

Group	Sham Needling	Dry Needling	<i>P</i> ^a
Total no. subjects	18	17	
Age, yrs (range)	41.5 ± 10.4 (25–68)	46.4 ± 12.2 (22–68)	>0.05
Sex			
Male	7	7	>0.05
Female	11	10	>0.05
Side			
Right	10	11	>0.05
Left	8	6	>0.05
Pain duration, mos	6.8 ± 4.5	7.5 ± 3.9	>0.05
Initial pain intensity (0–10)	7.2 ± 1.4	7.3 ± 1.4	>0.05

^a Tested by Student's *t* test.

Data Analysis

The mean and standard deviation of the values for the pain intensity, pressure pain threshold, and ROM measurements were calculated. Student's *t* test was used for the comparison of the differences between the control and experiment groups and the differences between the data before and after needling. The changes in pain intensity, pain threshold, and ROM after needling were further normalized as follows: normalized scores = percentage of changes = [(data after treatment – data before treatment)/data before treatment] × 100%. After data normalization as shown above, the differences in the changes of pain intensity, pain threshold, or ROM between two groups were further compared by using the *t* test. The confidence interval was set at 95% (*P* < 0.05). All data were analyzed using the Statistical Package for the Social Sciences version 8.0 for Windows.

RESULTS

Demographic Data

In total, 35 patients (with a mean age of 43.9 ± 11.4 yrs) with unilateral shoulder pain caused by MTrPs in the upper trapezius muscle were enrolled in this study. The control group consisted of 18 patients (7 males and 11 females), and the experimental group consisted of 17 patients (7 males and

10 females). As shown in Table 1, the mean age was 41.5 ± 10.4 (25–68) yrs in the control group and 46.4 ± 12.2 (22–68) yrs in the needling group. Among these 35 patients, the duration of pain ranged from 3 to 18 mos, and the intensity of pain ranged from 5/10 to 10/10. There were no significant differences between the two groups regarding age, sex, side of involvement, pain duration, and pain intensity (*P* > 0.05).

Subjective Changes in Pain Intensity

Improvement was limited to one or two levels in the 12 patients (67%) with improvement in the control group, whereas the range of improvement was up to a five-level decrease in all but 2 patients (88%) in the treatment group. One of the patients in the needling group with initial pain intensity at 5/10 did not report pain immediately after treatment. Two in the needling group and 6 in the control group had no change in pain intensity after treatment.

As shown in Table 2, there was a significant decrease in the mean pain intensity after treatment in the needling group (*P* < 0.05), but not in the sham-needling group (*P* > 0.05). After normalization of data into normalized scores (percentage of improvement), the degree of improvement in the subjective pain relief was significantly (*P* < 0.05)

TABLE 2 Changes in pain intensity (0–10) after therapy

Group	Sham Needling (<i>n</i> = 18)	Dry Needling (<i>n</i> = 17)	Needling vs. Sham, <i>P</i> ^a
Before treatment	7.2 ± 1.4	7.3 ± 1.4	>0.05
After complete treatment	6.4 ± 1.0	5.2 ± 1.6	<0.05
Before vs. after, <i>P</i> ^b	>0.05	<0.005	
% change after treatment	10.0 ± 8.1	28.5 ± 21.8	<0.05

Values were mean ± SD. % change after treatment = (postdata – predata)/(predata) × 100%.

^a Tested by Student's *t* test.

^b Tested by paired *t* test.

TABLE 3 Changes in pain threshold (kg/cm²) after therapy

Group	Sham Needling (n = 18)	Dry Needling (n = 17)	Needling vs. Sham, P ^a
Before treatment	2.5 ± 0.6	2.3 ± 0.5	>0.05
After complete treatment	2.9 ± 0.6	3.8 ± 0.8	<0.05
Before vs. after, P ^b	>0.05	<0.005	
% change after treatment	15.8 ± 11.3	67.8 ± 38.8	<0.05

Values were mean ± SD. % change after treatment = (postdata - predata)/(predata) × 100%.

^a Tested by Student's *t* test.

^b Tested by paired *t* test.

higher in the needling group than the control group.

Changes in Pressure Pain Threshold

In the control group, one patient had a reduced pain threshold (dropped from 4.3 to 4.2 kg/cm²), whereas another patient had no change in pain threshold (2.4 kg/cm²). However, every patient in the needling group had an increased pain threshold after treatment. Table 3 demonstrates the changes in pressure pain thresholds after treatment in both groups. The mean pain threshold was significantly ($P < 0.05$) increased after treatment in the needling group, but not in the control group ($P > 0.05$). There was a significantly ($P < 0.05$) higher degree of improvement (normalized scores) in the pressure pain threshold in the needling group than in the control group. Analysis of the differences between the first and the last threshold data from three repeated threshold measurements revealed no evidence of an increase of the pressure pain threshold. Therefore, a therapeutic effect of repeated threshold measurement was not observed in this study.

Objective Changes in ROM

Five patients (28%) in the control group had no improvement in the ROM of neck side bending after treatment, whereas only one patient in the needling group had no improvement. As listed in Table 4, there was a significant increase in the mean ROM after treatment in the needling group

($P < 0.05$), but not in the sham-needling group ($P > 0.05$). The degree of improvement (normalized scores) in the ROM of neck side bending was significantly ($P < 0.05$) higher in the needling group than in the control group.

DISCUSSION

Important Findings in This Study

In this study, we found that dry needling of a distal MTrP in the extensor carpi radialis longus muscle could inhibit the irritability of a proximal one in the ipsilateral upper trapezius muscle based on both subjective and objective measurements on the proximal MTrP. These findings further support the spinal cord connections among different MTrPs.

Previous Related Studies

In a single case report, Kuan and Hong²⁵ demonstrated the effectiveness of MTrP injection into distal MTrPs for reducing the pain intensity of proximal MTrPs in the shoulder muscles for a patient of severe myofascial pain in the shoulder and arm associated with reflex sympathetic dystrophy. Another single-case report by Tseng et al.²⁶ also described the successful suppression of severe myofascial pain in the upper trapezius muscle by remote dry needling of MTrPs in the ipsilateral forearm and hand muscles. Recently, Chou et al.²⁷ reported a fibromyalgia patient with severe shoulder pain who was treated with modified acupunc-

TABLE 4 Changes in range of motion (degrees) after therapy

Group	Sham Needling (n = 18)	Dry Needling (n = 17)	Needling vs. Sham, P ^a
Before treatment	46.9 ± 12.7	45.9 ± 10.3	>0.05
After complete treatment	50.6 ± 11.7	57.4 ± 13.1	<0.05
Before vs. after, P ^b	>0.05	<0.005	
% change after treatment	9.5 ± 13.2	25.8 ± 16.8	<0.05

Values were mean ± SD. % change after treatment = (postdata - predata)/(predata) × 100%.

^a Tested by Student's *t* test.

^b Tested by paired *t* test.

ture therapy (similar to the MTrP injection technique described by Hong) to the acupuncture points (AcPs) in the forearm muscles and had an excellent end result. Up until now, our study is the first sham-controlled study with objective assessment to confirm this remote effect.

Issue of Hyperstimulation Analgesia

Hyperstimulation analgesia is an effective way for pain control.²⁸ The site of hyperstimulation can be at the painful region (such as in trigger point injection) or at a remote site (such as in acupuncture). It has been demonstrated that painful heterotopic tonic stimuli decrease pain induced by phasic noxious stimulation applied extrasegmentally as a consequence of diffuse noxious inhibitory control.²⁹⁻³³ In our study, a similar effect was obtained by using phasic high-pressure needle stimuli to a remote site. Previous studies have further suggested that the greater the pain intensity of the heterotopic stimulation the greater the diffuse noxious inhibitory control.³⁴⁻³⁶ High-speed needle insertion, as suggested by Hong^{5,6} for MTrP injection, is an effective technique in providing high-pressure stimulation. In this study, we also applied a similar technique for dry needling. Using this technique of needling, an LTR can be elicited each time when the needle tip is quickly inserted into a certain site of the MTrP region because the rapid movement (force = mass × acceleration) of a needle with a tiny tip (pressure = force/area) definitely can provide very high-pressure stimulation. When an LTR is elicited during needling of an MTrP, it is frequently associated with a sharp pain or discomfort and frequently associated with a referred pain with patterns similar to those elicited by snapping palpation of the MTrP.¹⁴ These sites that responded to needle stimulation with eliciting LTRs and referred pain in one MTrP region have been considered to be sensitized nociceptors.^{37,38} Strong stimuli applied on the sensitive nociceptors can generate strong impulses, and these impulses transmit into the spinal cord. It is likely that these impulses subsequently break the vicious cycle of the neural circuit responsible for MTrP (the hypothetical "MTrP circuit")^{8,9} in a manner similar to hyperstimulation analgesia. This is probably the mechanism of remote pain control as demonstrated in this study.

Dry Needling to an MTrP vs. Acupuncture to an AcP

The neural connections (hypothetical MTrP circuits) in the spinal cord for different MTrPs are probably similar to the acupuncture "meridians" system. The similarity between acupuncture and MTrP injection or dry needling has been documented.^{3,7,28,39,40} In fact, many MTrPs are actually

AcPs including the tradition AcPs in the meridians and "a shi points." Melzack²⁸ has reported a high degree (71%) of correspondence between MTrPs and AcPs. However, after reviewing acupuncture textbooks, Birch⁴¹ concluded that the claimed 71% correspondence of trigger points to AcPs was conceptually not possible and that the only class of AcPs that could were the *a shi* points. On the other hand, Dorsher⁴² compared 255 MTrPs with 747 AcPs and found that 92% of the 255 MTrPs had anatomically corresponding AcPs. In his study, complete or near-complete agreement in the distributions of the myofascial referred-pain patterns and acupuncture meridians was found for 76% of corresponding points.⁴² The fixed pattern of the referred pain in a specific MTrP implies that there are fixed connections among certain sensory neurons in the spinal cord.⁷ These connections are probably the same as the connections among different AcPs of the same meridian. It has been suggested that latent synaptic connections among wide dynamic range neurons are responsible for the generation of allodynia, hyperesthesia, and referred pain via central sensitization.^{43,44} The connections among the afferents from different MTrPs or AcPs are probably similar to those connections for central sensitization. Another similarity between MTrPs and AcPs is that the subjective feelings when an LTR is elicited during MTrP injection are similar to those when the "De-Qui" effect is elicited during acupuncture therapy. These feelings include soreness, fullness, numbness, tingling, paresthesia, and muscle twitching.

Limitation in This Study

It is unclear whether needling to a remote "non-MTrP and non-AcP" site can also elicit a similar effect because we did not have a control group with needling on this kind of remote points. Clinically, an MTrP or an AcP (*a shi* point) is relatively much more tender than the surrounding sites. An algometer study also suggested that the MTrP is the most tender spot.⁴⁵ Therefore, a higher-pressure stimulation on the surrounding nonsensitive point would be required to induce a remote effectiveness.

The long-term effectiveness of remote acupuncture has been reported.^{16,18} Unfortunately, we did not perform a follow-up study because this study emphasized the evidence of remote effects of needling rather than the therapeutic effectiveness.

In a future study, we should include the above two issues to provide a better scientific basis for the remote acupuncture therapy.

CONCLUSIONS

In this study, we demonstrated that dry needling of a distal MTrP in the extensor carpi radialis

longus muscle could reduce the irritability of a proximal MTrP in the upper trapezius muscle. It can support the existence of neural connections in the spinal cord among the afferents from different MTrPs. It may further clarify the physiologic basis of the remote effectiveness of dry needling or of acupuncture therapy for pain control.

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Erratum

Musculoskeletal Education for Medical Students: Erratum

In the article that appears on page 791 of the October 2009 issue, the sample objectives for an advanced clerkship were listed on page 794. These sample objectives were modified from those developed at the University of Washington School of Medicine by Teresa Massagli, MD. The authors wish to credit her for this work.

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DOI: 10.1097/PHM.0b013e3181cbcec3



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October 5, 2009

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RE: Task Force Report on 'Dry Needle' Acupuncture By Physical Therapist

Dear Directors of the Oregon Board of Medicine:

This letter contains a summary of the findings of the American Association of Acupuncture and Oriental Medicine's (AAAOM) Task Force charged with investigating attempts by Physical Therapists to add needle injection/acupuncture ('dry needling') into the scope of practice for Physical Therapists. The AAAOM is the national organization representing acupuncturists in the United States.

The most recent attempt occurred in Oregon, where the Oregon Board of Physical Therapy, at the request of certain Physical Therapists ("PTs"), gave an opinion that 'dry needle technique' was within the scope of PTs practice, if they had appropriate training. It should be noted that the Board did not actually adopt this suspect and unsupportable opinion in their Administrative Rules, nor did the OPT Board stipulate exactly what 'appropriate training' meant. It is the understanding of this Task Force that 'appropriate training' for acupuncture needle insertion has been legally decided by the State of Oregon Legislature and is published and regulated pursuant to the Oregon licensed acupuncture statute (ORS 677.757 to 677.770) and its applicable regulations as promulgated by the Oregon Board of Medicine.

The medical literature clearly identifies 'dry needling' as acupuncture.¹ Accordingly, this Task Force can find no authority for Physical Therapists to administer acupuncture, or any type of needle insertion through the skin. It is historically and statutorily clear that "physical therapy interventions" were never intended nor implied to include 'needle insertion,' (whether that needle be 'wet' or 'dry'). There is no accredited school of Physical Therapy that offers an extensive course or clinical training in 'dry needle' technique, much less any complex and extensive didactic or clinical training in acupuncture. The current training programs on Dry Needle Technique for Physical Therapists in the US and in Europe are made up of a one-weekend seminar.²

Licensed acupuncturists undertake rigorous credentialing and examination processes—particularly by graduate level educational programs that are programmatically accredited, requiring four to six years to complete (after completing the prerequisite college course work required for matriculation). These training programs typically involve at least two years of clinical rotation, and most colleges award a master's of science degree. The minimum program for acupuncture allowed by the Accreditation Commission of Acupuncture and Oriental Medicine is 2625 hours, 600 of which are in the clinic.³ Licensed acupuncturists in the U.S. are highly trained clinical specialists who provide care

¹ <http://www.ncbi.nlm.nih.gov/pubmed/15108608>

² <http://www.dryneedlingcourse.com/>

³ <http://www.acaom.org/PdfVersion/Structure%20Scope%20and%20Standards%20Manual%2007-08-08.pdf>

based on course work in biomedical sciences in addition to traditional Asian medicine. Several European programs that teach 'dry needle' technique openly admit that it is acupuncture.⁴

What physical therapists are trying to do is to include acupuncture in their scope of practice by calling it a different name, thereby circumventing the extensive training required by both Physicians and Acupuncturists to insert needles into patients for the treatment of health issues.

This Task Force has contacted Michael J. Schroeder, the Vice-president and Legal Counsel for Allied Professional Services (APS). Allied Professional Services provides malpractice insurance for Physical Therapists. Mr. Schroeder stated that APS would revoke the malpractice insurance of any Physical Therapist engaged in the use of 'dry needle' technique. He stated that this is because of the "risk of public endangerment created by a Physical Therapist engaging in a medical procedure for which they have no adequate education or training."⁵

Furthermore, it is a violation of most professional codes of conduct throughout the U.S. to engage in, or advertise a professional service, unless an individual is adequately credentialed and qualified to do so. Therefore the advertisement by a PT for 'dry needling' can be reasonably considered unethical misrepresentation and/or misleading to the public. The performance of 'dry needling' by an unqualified and/or credentialed PT can reasonably be deemed unethical and negligent conduct.

Based upon the above information, this Task Force concludes that if the Physical Therapy Board continues to allow physical therapists with one weekend of training to insert needles into patients, this will create a serious endangerment for the public.

Sincerely,



Michael Taramina, Esq.
AAAOM Legal Counsel



Gene Bruno, OMD, LAc

Task Force Member

⁴ <http://www.cf.ac.uk/sohcs/degreeprogrammes/continuingeducation/2011courses/acupuncture-dry-needle-therapy.html>

⁵ Michael Schroeder - V.P of Allied Professional Services 714-647-6488



May 17, 2011

AAAOM

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American Association of
Acupuncture & Oriental Medicine

American Association of Acupuncture and Oriental Medicine (AAAOM) Position Statement on Trigger Point Dry Needling (TDN) and Intramuscular Manual Therapy (IMT)

1. Acupuncture as a technique is the stimulation of specific anatomical locations on the body, alone or in combination, to treat disease, pain, and dysfunction.
2. Acupuncture as a technique includes the invasive or non-invasive stimulation of said locations by means of needles or other thermal, electrical, light, mechanical or manual therapeutic method.
3. Acupuncture as a field of practice is defined by the study of how the various acupuncture techniques can be applied to health and wellness.
4. Trigger Point Dry Needling and Intramuscular Manual therapy are by definition acupuncture techniques.
5. Trigger Point Dry Needling and Intramuscular Manual Therapy are by definition included in the Field of Acupuncture as a field of practice.

The AAAOM endorses the educational standards set for the practice of Acupuncture by the United States Department of Education recognized Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM).

The AAAOM endorses the Institute for Credentialing Excellence (ICE)'s National Commission on Certifying Agencies (NCCA) recognized certification standards set forth by the National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM).

Recently, it has come to the attention of the AAAOM that regulatory boards have started to recognize Acupuncture by other names, such as “dry needling” and “trigger point dry needling.” Forty-four (six pending) states plus the District of Columbia have already statutorily defined Acupuncture and most have defined the educational and certification standards required for licensure by the widely accepted aforementioned standards. Current medical literature is consistent with the definitions of Acupuncture provided by the state practice acts and the AAAOM, which clearly identifies “dry needling” as Acupuncture.^{1 2 3 4 5 6 7 8 9 10 11 12 13}

Trigger Point Dry Needling and Intramuscular Manual Therapy are re-titlings and re-packagings of a subset of the acupuncture techniques described in the Field of Acupuncture as “*ashi* point needling.” A reasonable English translation of *ashi* points is “trigger points”, a term used by Dr. Janet Travell in her landmark 1983 book *Myofascial Pain Dysfunction: The Trigger Point Manual*⁶. Dorsher et al⁴, determined that of the 255 trigger points, listed by Travell and Simons, 234 (92%) had anatomic correspondence with classical, miscellaneous, or new Acupuncture points listed in Deadman et al⁷.

Other authorities describe dry needling as Acupuncture. Mark Seem discussed dry needling in *A New American Acupuncture* in 1993⁸. Matt Callison describes dry needling in his *Motor Points Index*⁹ as does Whitfield Reaves in *The Acupuncture Handbook of Sports Injuries and Pain: A Four Step Approach to Treatment*¹⁰. Yun-tao Ma, author of *Biomedical Acupuncture for Sports and Trauma Rehabilitation Dry Needling Techniques*, describes dry needling as Acupuncture and provides a rich historical explanation¹¹. Chan Gunn sought to create language more readily accepted in the West in a 1980 article¹². These examples make it clear that there is a literary tradition in the Field of Acupuncture that uses the term “dry needling” as a synonym for a specific, previously established Acupuncture technique.

The AAAOM has the following additional specific concerns: 1) No standards of education have been validly determined to assure that Physical Therapists (PT) using TDN are providing the public with a safe and effective product; 2) There is a clear effort to redefine identical medical procedures and thereby circumvent or obscure



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established rules and regulations regarding practice; and 3) In many states, addition of TDN to PT practice is a scope expansion that should require legislative process, not a determination by a PT Board.

The U.S. Department of Education recognizes ACAOM as the sole accrediting agency for Acupuncture training institutions as well as their Master's and Doctoral Degree programs.^{13 14} Training in Acupuncture, which has been rigorously refined over the course of hundreds of years internationally and forty years domestically, is well established and designed to support safe and effective practice.^{15 16} Attempts to circumvent Acupuncture training standards, licensing or regulatory laws by administratively retitling acupuncture as "dry needling" or any other name is confusing to the public, misleading and creates a significant endangerment to public welfare.

The actual risk has already been investigated by at least one malpractice insurance company that has stated it will cancel policies for Physical Therapists "engaging in a medical procedure for which they have no adequate education or training."¹⁷ Recent actions by state medical regulatory authorities have identified and acted upon the aforementioned risk.³

In conclusion, the AAAOM strongly urges legislators, regulators, advisory boards, advocates of public safety, and medical professional associations to carefully consider the impact of these actions.

¹ <http://www.ncbi.nlm.nih.gov/pubmed/15108608>

² http://www.Acupuncture.org.au/zone_files/Download_Icons/jing-luo_march_2011_web.pdf pg. 10

³ <http://www.oaaom.com/wp-content/uploads/2010/06/DryNeedling.pdf>

⁴ Dorsher PT. *Trigger Points And Acupuncture Points: Anatomic And Clinical Correlations*. Medical Acupuncture. 2006;17(3).

⁵ Deadman P, Al-Khafaji M, Baker K. *A Manual of Acupuncture*. Kingham, Oxfordshire Journal of Chinese Medicine Publications; 1998.

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⁸ Seem M. *A New American Acupuncture: Acupuncture Osteopathy, the Myofascial Release of the Bodymind*. Boulder, CO: Blue Poppy Press; 1993.

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¹² Gunn CC, Milbrandt WE, Little AS, Mason KE. *Dry Needling of Muscle Motor Points for Chronic Low-Back Pain: A Randomized Clinical Trial With Long-Term Follow-Up*. Spine. 1980;5(3):279-91.

¹³ <http://ope.ed.gov/accreditation/>

¹⁴ <http://www.aaaom.org/about/>

¹⁵ <http://www.aaaom.org/documents/accreditation-manual.pdf>

¹⁶ <http://www.nccaom.org/applicants/eligibility-requirements>

¹⁷ Letter from Allied Professional Services [on file at AAAOM]